Improving and Measuring Osteoporosis Management

Normal Bone

Bone with Osteoporosis

The Joint Commission

National Pharmaceutical Council
FOREWORD

If your patient is a postmenopausal female living in North America, her chances of sustaining a fractured hip are greater than her chances of being diagnosed with breast cancer. In fact, her chances of sustaining a fractured hip are greater than her chances of being diagnosed with breast, uterine, or ovarian cancer combined.

Osteoporosis, the disease underlying most hip fractures, is often overlooked – even when there are preceding fractures of the wrist or vertebra, and even after a hip fracture occurs. On average, only 20% of the patients with these fragility, or low-impact fractures, are ever tested for or treated for osteoporosis.

How many of your patients are among the 10 million people (eight million women and two million men) estimated to be living with osteoporosis in the U.S.?

The financial cost of these fractures is staggering. The estimated national direct care expenditures (including hospitals, nursing homes, and outpatient services) for osteoporotic fractures are $18 billion per year in 2002 dollars, and costs are rising. The cost of these fractures is even higher in terms of lives lost or lives adversely impacted by both physical and psychological impairments associated with osteoporosis.

It’s time for a change in how osteoporosis is prevented, detected, and treated.

With an unrestricted educational grant from the National Pharmaceutical Council (NPC), The Joint Commission used its established, consensus-driven and evidence-based processes to develop 10 osteoporosis performance measures suitable for use by a variety of health care providers, including hospitals, home care agencies, rehabilitation facilities, nursing homes, and physician offices. Constructed by a technical advisory panel of expert physicians, dietitians, pharmacists, nurses, and others experienced in osteoporosis management and measure development, these measures are intended to be voluntarily used to increase the rates by which osteoporosis is diagnosed and treated, and to decrease the rates by which hip and other fragility fractures rob affected patients of their quality of life.

This monograph presents practical approaches to an increasing public health problem. It does not contain a review and critique of the few previously published clinical practice guidelines. Those who wish further clinical readings are referred to any of the publications listed in the bibliography, relevant tables, and to osteoporosis-specific material available elsewhere in the medical literature.

The mission of The Joint Commission is “to continuously improve the safety and quality of care provided to the public through the provision of health care accreditation and related services that support performance improvement in health care organizations.” We salute those professionals who are already engaged in helping patients by improving osteoporosis management, and this material is offered to augment those efforts. For those professionals who are now embarking on such a program, we hope you find these materials useful in your initial efforts.

A Note about Terminology

The term “patient” is used throughout this monograph to refer to inpatients, outpatients, clients, residents, and/or members.
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DISCLAIMER

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Since 1953, the NPC has sponsored and conducted scientific, evidence-based analyses of the appropriate use of pharmaceuticals and the clinical and economic value of pharmaceutical innovation. NPC provides educational resources to a variety of stakeholders, including patients, clinicians, payers and policy makers. More than 20 research-based pharmaceutical companies are members of the NPC.

The Joint Commission evaluates and accredits nearly 15,000 health care organizations and programs in the United States. An independent, not-for-profit organization, The Joint Commission is the nation’s predominant standards-setting and accrediting body in health care. Since 1951, The Joint Commission has maintained state-of-the-art standards that focus on improving the quality and safety of care provided by health care organizations.

This monograph is designed for informational purposes and is not intended as a substitute for medical or professional advice. It is intended for a professional audience; non-professional readers should consult a qualified health care professional before making any decisions on any specific matter of osteoporosis care. In addition, these measures, while constructed in accordance with The Joint Commission’s evidence-based approach to development, expert panel consensus, and stakeholder comment and review, have not yet been subject to The Joint Commission’s rigorous field testing process to ensure reliability and validity of data elements. Therefore, the presentation of each measure is formatted differently than the traditional The Joint Commission measure format, to allow the professional audience to discern fully-tested and specified measures from those awaiting reliability and validity testing.

Inclusion of any reference should not be construed as an endorsement of any product, treatment, medication, or program discussed therein. The inclusion of a product name or service should not be construed as an endorsement of such product or service, nor is failure to include the name of a product or service to be construed as disapproval. The Joint Commission has worked to ensure that this monograph contains useful information, but this monograph is not intended as a comprehensive source of all relevant information. In addition, because the information contained herein is derived from many sources, The Joint Commission cannot guarantee that the information is completely accurate or error free. The Joint Commission is not responsible for any claims or losses arising from the use of, or from any errors or omissions in, this monograph.
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PART I. CLINICAL CONSIDERATIONS IN OSTEOPOROSIS MANAGEMENT

Introduction

Despite ongoing advances in osteoporosis detection and treatment options, studies suggest that osteoporosis (a systemic skeletal disease leading to fracture, morbidity, and excess mortality) continues to be poorly managed, undertreated, and underdiagnosed. Between 5.2% to slightly more than 50% of women with fragility fractures are ever screened or treated for osteoporosis. The increase in clinical information related to osteopenia (a less severe level of bone loss) and osteoporosis, as well as recent press coverage, has resulted in heightened awareness among health care professionals and the public that this critical issue must be addressed, and that current approaches to osteoporosis management must be improved.

At the most fundamental level, improving osteoporosis management is simply the right thing to do. Given the incidence of low-impact, or fragility, fracture, and findings that many patients with fragility fracture are never tested or treated for osteoporosis, or when treated fail to persist in compliance with medication, improvement in care is a cornerstone of health care’s humanitarian mission.

From a clinical standpoint, care improvement is essential due to the prevalence of undesirable outcomes, such as fracture, morbidity, and excess mortality. Improved management of osteoporosis is necessary to respond to an aging population's increasing expectations for optimal health care and new standards or requirements, such as those set by insurers, government regulatory bodies, and other stakeholder groups.

The key to judging the success of improvement efforts in any organization is measurement, because accurate data underpin all aspects of the change and improvement processes. This monograph is designed to help health care organizations implement the performance measurement processes they need to achieve their goal of improving osteoporosis management, and to delineate the evidence-based measures that can be used in such programs to effect improvement in osteoporosis care. This monograph provides:

- An overview of osteoporosis basics and extant clinical guidelines and measures for osteoporosis care.
- Recommended evidence-based measures to improve osteoporosis care.
- An overview of methods for measuring performance and principles of organizational improvement that can be applied to osteoporosis management.
- References and other sources for more detailed information on selected topics.

This monograph is written for clinicians with varying expertise in osteoporosis management, quality improvement (QI) professionals, researchers, and others involved in osteoporosis management and performance assessment, improvement, and education. Because of the broad intended audience, some readers may find aspects of the monograph too technical or too clinical, while others may find it overly simplistic. Similarly, specific sections may be of greater interest to some readers than others, depending on one’s care setting, role, and experience in osteoporosis management and improvement efforts. Nevertheless, we hope that readers will find the material relevant and helpful in their efforts to understand osteoporosis and implement improved osteoporosis methodologies.

Osteoporosis affects 44 million Americans (more than California’s population) at a cost of $17 billion annually.
Given the rapidly-changing knowledge base regarding osteoporosis pathogenesis, treatment, and management, certain aspects of osteoporosis care are not directly addressed in this monograph, but are identified as areas for further research and delineation. Such areas include:

- Osteoporosis detection and management in men
- Optimal bone mineral density (BMD) testing intervals for those at risk for low bone mass due to age or medical history (such as transplantation or surgery for obesity)
- Childhood osteoporosis
- Compliance issues for those who are prescribed pharmacotherapy for osteoporosis
- Delineation of any relationship between bisphosphonates prescribed for treatment of osteoporosis and the occurrence of osteonecrosis of the jaw

Similarly, although well-researched and documented, it is beyond the scope of this monograph to delineate acute fracture care and post-operative rehabilitative care. Instead, the reader is referred to the abundant specialty literature, such as Health Professional’s Guide to Rehabilitation of the Patient with Osteoporosis (available from the National Osteoporosis Foundation (NOF), for further reading.

Section I. Background and Significance of Osteoporosis

A. Overview

Osteoporosis is a skeletal condition of growing interest and concern. Called “the silent disease,” “brittle bone disease,” or “thinning of the bones,” it often lacks symptoms until a fracture occurs. It is a disease in which the microarchitecture of bone becomes structurally faulty and weakened, and becomes susceptible to minor forces that can cause fracture. Its precursor, osteopenia, exhibits the same microarchitectural faults, but to a lesser degree. Both of these forms of bone loss, however, pose significant challenges to the health care community.
B. Definition

**Diagnostic Criteria**

The World Health Organization (WHO) has proposed criteria for the diagnosis of osteopenia, osteoporosis, and severe osteoporosis in women. All classifications of bone density incorporate the results of a BMD test. Results are expressed as a T-score, which is the number of standard deviations (SDs) above or below the peak bone mass of a young adult reference standard. Table 1, below, delineates WHO’s Diagnostic Criteria for Osteoporosis.

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<td>Normal</td>
<td>BMD value within 1 SD of the young adult reference mean (T-score &gt;-1)</td>
</tr>
<tr>
<td>Osteopenia</td>
<td>BMD value more than 1 SD below the young adult mean but less than 2 SDs below this value (T-score &lt;-1 and &gt;-2.5)</td>
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<td>Osteoporosis</td>
<td>BMD value 2.5 SDs or more below the young adult mean (T-score &lt;2.5)</td>
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<td>Severe Osteoporosis</td>
<td>BMD value 2.5 SDs or more below the young adult mean in the presence of one or more fragility fractures</td>
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*SD = standard deviation


Note that according to the WHO definition, the diagnosis of severe osteoporosis results from a combination of BMD results and fracture history.

**Types**

There are two principal types of osteoporosis. Primary osteoporosis arises as a result of aging and other risk factors and is not associated with any other disease processes. Secondary osteoporosis occurs as a result of some other underlying disease process, such as malabsorption syndromes or hyperparathyroidism. When osteoporosis is diagnosed, clinicians can be challenged to delineate the underlying causes of osteoporosis. Testing in secondary osteoporosis is discussed fully in Section III, Primary Prevention, page 14.

**C. Prevalence**

Prevalence estimates vary. Projections about increasing numbers of cases of osteoporosis in the future are well-founded, since the population in general is aging and age itself is a risk factor. It is estimated that the current number of osteoporosis cases in the U.S. alone is at 10 million, with another 34 million individuals at risk of fracture due to low bone mass. Osteoporosis incidence increases with age, affecting:

- 37% of women between the ages of 50 and 59
- 50% between the ages of 60 and 69
- 75% between ages 70 and 79
- and 87% of women older than 80 years of age

Men are not immune from the disease, as 5% of men on Medicare in 2001 had an osteoporosis diagnosis. Estimates are that the number of persons older than age 50 with osteoporosis will increase to 12 million by 2010 and to nearly 14 million by 2020.
The most significant outcome of low bone mass is fracture – most commonly at the hip, radius, and vertebra. In the U.S., a Caucasian female has a 17% lifetime chance of a hip fracture; a Caucasian male has a 6% chance. In their lifetimes, 30% to 50% of women and 15% to 30% of men will incur an osteoporosis-related fracture. In the U.S., 1.5 million fractures annually can be attributed to osteoporosis – 700,000 vertebral fractures and 800,000 fractures of other sites, including 300,000 hip fractures. Of these 300,000 hip fractures, estimates are that 14% of patients (or 42,000 patients) will die within one year as a result of the fracture, independent of any underlying causes other than osteoporosis.

D. Economic Impact
As a driver of health care costs now and in the future, the economic impact of osteoporosis is significant. Current direct costs of hip fracture treatment in the United States are up to $18 billion. By 2020, the cost of hip fracture treatment is expected to range from $31 billion to $62 billion. The cost of all osteoporosis-related fractures is currently equivalent to the costs of cardiovascular disease and asthma.

Section II. Etiology and Assessment

A. Pathophysiology
There are two structural types of bone – cortical bone and trabecular bone. Cortical bone is the thin outer layer of compact bone, while trabecular bone is found underneath the bone surface. Trabecular bone is a lattice-like structure which, after maturity, is constantly remodeled and replaced at approximately 120-day intervals. This remodeling occurs as a result of a complex interplay of osteoblasts (those cells responsible for new bone formation) and osteoclasts, which destroy and remove old bone.

Peak bone mass is the amount of bone tissue present at the end of skeletal maturation. It is a major determinant of the risk of fracture due to osteoporosis, since the mass of bone tissue at any time during adult life is the difference between the amount accumulated at maturity and that lost due to the aging process. There is, therefore, considerable interest in exploring ways to increase peak bone mass.

During maturity, osteoblastic and osteoclastic activities are in balance, maintaining normal bone integrity. However, as a result of aging or other biochemical factors (e.g., inadequate nutrient intake and absorption, medications, and loss of natural hormones), osteoblastic activity is exceeded by osteoclastic activity. The body maintains serum calcium concentration at the expense of bones, and any new bone formed contains less mineral content, so that bones become less dense and less mineralized. This causes the trabecular bone to become structurally “thinner” and less able to withstand stressors, such as weight and impact, and fractures easily result. Once such fragility fracture (also known as a low-trauma fracture) occurs, the likelihood of another fracture occurring is substantially increased. One team of researchers found that women with a prevalent fracture and osteopenia had the same, if not greater, risk for future fracture as women with osteoporosis alone.

B. Risk Factors
There are several identified risk factors for the development of low bone mass. Chief among these is age itself. A recent study among 616 women, aged 60-94, found that for each year of increasing age, the fracture risk increases by 3%. Among women, the gradual loss of estrogen at menopause contributes significantly to this decline in bone integrity and is a principal factor in what Riggs and Melton proposed in 1983 as Type I involutional osteoporosis. The reduction in circulating estrogen triggers osteoclast activation and bone resorption, resulting in rapid bone loss at a rate of 1% to 5% yearly; this phase lasts from four to eight years.

The second phase, a more gradual bone loss, occurs 10 to 20 years after menopause and affects men as well as women. This Type II osteoporosis is marked by a
rise in parathyroid hormone (PTH) levels, increase in bone turnover, and a decline in osteoblastic activity causing reduced bone formation. In addition to age, there are several other risk factors for the development of low bone mass, including lifestyle, nutrition, other medical conditions, and medication use (see Table 2, below). Although there are myriad risk factors identified in various studies, the principal factors identified most consistently in the professional literature are:

- Asian or Caucasian race
- History of parental hip fracture
- Personal history of fragility fracture after age 40
- BMI <19
- Long-term use of steroids or other medications (i.e., anticonvulsants, heparin, others)
- Malabsorption disorders
- Solid organ or bone marrow transplantation
- Alcoholism
- Hyperparathyroidism
- Chronic liver or kidney disease
- Sedentary lifestyle
- Hypogonadism

Persons of African descent have higher bone mass and lower rates of fracture. Asian women have lower bone mass than Caucasian women, but, interestingly, the rate of hip fractures is not proportionally higher. Theories to explain this discrepancy include shorter hip-axis length in the Asian women, previous activity levels that were higher, and the cultural practice of taking care of the elderly and not allowing them to leave their beds, thereby reducing the opportunity for falling. Hispanic women have approximately half as many fractures as Caucasian women, but this is not explained by any difference in bone density.

Table 2. Significant Risk Factors for Osteoporosis

<table>
<thead>
<tr>
<th>General Factors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maternal hip fracture</td>
</tr>
<tr>
<td>Family history of osteoporosis</td>
</tr>
<tr>
<td>Personal history of fragility fracture as an adult</td>
</tr>
<tr>
<td>Postmenopausal status in women</td>
</tr>
<tr>
<td>Advancing age, particularly age 65 and older</td>
</tr>
<tr>
<td>Asian or Caucasian derivation</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Lifestyle Factors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cigarette smoking</td>
</tr>
<tr>
<td>Inadequate physical activity</td>
</tr>
<tr>
<td>Inability to rise from a chair</td>
</tr>
<tr>
<td>Prolonged amenorrhea</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Nutritional Factors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Excess caffeine intake</td>
</tr>
<tr>
<td>Excess alcohol use</td>
</tr>
<tr>
<td>Low calcium intake</td>
</tr>
<tr>
<td>BMI &lt;19</td>
</tr>
<tr>
<td>Low body weight (127 pounds)</td>
</tr>
<tr>
<td>Vitamin D deficiency</td>
</tr>
</tbody>
</table>

Table 2 continued on page 12
Medical Conditions
- Malabsorption syndromes (includes weight-loss surgery and gastrectomy)
- Eating disorders (anorexia nervosa)
- Hyperparathyroidism
- Hyperthyroidism
- Hypogonadism (includes estrogen deficiency)
- Solid organ or bone marrow transplantation
- Amyloidosis
- Ankylosing spondylitis
- Chronic Obstructive Pulmonary Disease
- Congenital porphyria
- Cushing’s syndrome
- Female athlete triad
- Gaucher disease
- Hemochromatosis
- Hemophilia
- Hypophosphatasia
- Idiopathic scoliosis
- Inflammatory bowel disease
- Insulin-dependent diabetes mellitus
- Lymphoma, leukemia
- Mastocytosis
- Multiple myeloma
- Multiple sclerosis
- Pernicious anemia
- Rheumatoid arthritis
- Severe liver disease (especially primary biliary cirrhosis)
- Spinal cord transection
- Sprue
- Stroke
- Thalassemia
- Thyrotoxicosis
- Weight loss
- Dialysis

Medications
- Long-term glucocorticoid use
- Anti-seizure medication (phenobarbital, phenytoin)
- Aromatase therapy for breast cancer
- GnRH therapy for prostate cancer
- Aluminum
- Cytotoxic drugs
- Immunosuppressants
- Long term heparin use
- Proton pump inhibitors
- Parenteral progesterone
- Supraphysiologic thyroxine doses
- Tamoxifen (premenopausal)
- Total parenteral nutrition

Adapted from: References 18, 34, 39, 40 and 43. Siris E. Proton pump inhibitors added as personal communication. July 2007.
C. Diagnosis

**Bone Mineral Density Testing Modalities**

There is a variety of diagnostic testing options for the determination of bone density. Bone density determinations may be used for diagnosis of osteoporosis, determination of fracture risk, and monitoring progress for those using pharmacotherapy.

**Single and Dual-energy X-ray Absorptiometry**

Single-energy X-ray absorptiometry (SXA) and dual-energy X-ray absorptiometry (DXA or DEXA) are methods for measuring the mineral content of the entire skeleton as well as of specific sites. Since the scan is two-dimensional, this is an areal density measurement rather than a volumetric density. SXA measures density at appendicular sites, such as the heel or wrist, while DXA measures spine, hip, and total body density.23

The gold standard for diagnosis and determination of fracture risk is DXA performed at the hip (femoral neck) and lumbar spine. DXA is generally the method of choice because it has low radiation exposure, is fast, and renders precision measurements at the spine, hip, radius, or other peripheral site. DXA at the hip is the best predictor of hip fracture. There are also portable DXA machines that measure bone density at other sites, such as the forearm or heel, but the ability to predict fracture risk from results at these peripheral sites is unclear.16

It is important, when performing sequential testing, to repeat testing on the same machine when possible, since test results from machine to machine and facility to facility can vary significantly. Further, rigorous quality control measures for DXA imaging equipment are required. The reader is directed to resource materials from the International Society for Clinical Densitometry (available at www.iscd.org) for further details on quality control recommendations for equipment.

**Quantitative Ultrasound of the Heel**

In prospective studies, quantitative ultrasound (QUS) at the heel predicted hip fracture and all non-spine fractures nearly as well as DXA measured at the femoral neck. QUS offers the advantages of portability, economy, and non-use of ionizing radiation. As a result, QUS has become very popular for mass screenings in shopping malls and at health fairs. While QUS can be used to estimate the risk of fracture in postmenopausal women and older men, it cannot be used as a diagnostic tool nor can it be used to monitor progress on therapy. Further, the T-scores (see Bone Mineral Density Testing Results, page 14) generated by QUS are not comparable to the T-scores generated by DXA because these technologies measure different properties of bone. DXA measures bone mineral content while QUS measures BMD and properties of bone strength by assessing the speed and attenuation of sound as it passes through bone.24

For DXA of the femoral neck and QUS of the heel, a result in the osteoporotic range is independently associated with an increased short-term probability of hip fracture.

**Quantitative Computed Tomography**

Cancellous bone in the spine and radius is highly suitable for assessment by quantitative computed tomography (QCT). QCT has been applied to the spine and appendicular skeleton, but not to the hip. QCT measures true volumetric density. This technique is suitable for monitoring response to treatment since it measures the cancellous bone that is more responsive to treatment. While QCT provides information on the macroarchitecture of bone, its major disadvantages are high radiation exposure, quality control problems, and high relative cost.25

QUS cannot be used to diagnose osteoporosis.
Magnetic Resonance Imaging
Magnetic resonance imaging (MRI) does not provide direct information on bone density (given the positive background emitted by all types of bone marrow), but it does provide some information on the structure of cancellous bone. MRI, at present, remains under investigation as a tool to measure bone density and is classified as a research procedure due to cost and complexity.23

Other modalities
There are other peripheral measures, such as radiographic absorptiometry (RA) and quantitative microdensity (QMD), that can predict the risk of non-spine fractures in general, but there are no data about the ability of these peripheral measurements to predict hip fracture.25

Bone Mineral Density Testing Results
The results of BMD tests are expressed as T-scores and Z-scores. T-scores represent the number of SDs that result when the patient’s test readings are compared to the test readings calculated against a reference standard for female, Caucasian, 20-29 years old (young normal) contained in the National Health and Nutrition Examination Survey (NHANES) III database. For example, a T-score of -1 indicates that the test result is 1 SD below normal. T-scores are used by the WHO to define osteoporosis as discussed previously.

Z-scores, on the other hand, are comparisons of SDs against gender- and ethnic-specific, age-adjusted databases. While T-scores are used to define osteoporosis in women, the Z-score should be used for diagnosis in children and in males less than 50 years of age. The result is expressed as the number of SDs from the expected age range.26

Bone Turnover Markers
As discussed earlier, the process of bone remodeling by osteoblasts and osteoclasts occurs constantly. It can be assessed by measurement of certain markers of both resorption and formation. Formation markers include osteocalcin and bone-specific alkaline phosphatase. Resorption markers include pyridinoline, deoxypyridinoline, amino-terminal telopeptide, and carboxy-terminal telopeptide. Unfortunately, these biochemical markers may not always show a significant change in patients on therapy and the markers, as biological agents, demonstrate both seasonal and circadian variability. Therefore, bone turnover markers may have utility in some patients to monitor progress in therapy and may be useful in clinical trials to monitor progress, but they cannot be used to diagnose osteoporosis and can only be used to monitor progress while on therapy in limited circumstances.27 According to findings of a study funded by the Agency for Healthcare Research and Quality, “no marker is accurate enough to reliably identify those individuals who will fail to respond to treatment,” and “no marker was associated with increased fracture risk consistently across all studies.”25

Section III. Osteoporosis Management
A. Prevention

Goals
Effective prevention strategies can be implemented during skeletal development in infancy, childhood, and later in life and are needed to minimize the physical, social, and economic consequences of osteoporosis. The following are goals of prevention programs:

- Optimize skeletal development and maximize peak bone mass at skeletal maturity
- Prevent age-related and secondary causes of bone loss
- Preserve the structural integrity of the skeleton
- Prevent fractures

**Approaches**

**Dietary**

Certain risk factors for osteoporosis are immutable; gender, ethnicity, and family history cannot be changed. However, two of the risk factors, low lifetime calcium intake and Vitamin D deficiency, can be modified.

**Calcium** - More than 99% of the body’s calcium is in the skeleton. When calcium intake is low, the skeleton is used as a reserve to meet the body’s needs. Persons with a low intake of calcium are thus at risk for osteoporosis. In the U.S., the average diet contains 600 mg of calcium compared with the recommended average daily intake of about 1000 mg to 1200 mg.

The preferable source of calcium is from food. It should be remembered, however, that not all calcium content in food is absorbed. Other factors, such as acid environment, caffeine intake, iron intake, oxalate intake, and other circumstances (such as aging) can affect the amount of calcium absorbed. As a result, food intake patterns need to be carefully evaluated. Calcium deficiency is difficult to identify since there are no direct, reliable measurements of calcium levels. However, women with low levels of Vitamin D, as measured by 25(OH)D levels, are unlikely to absorb calcium efficiently. While there is no consensus on criteria for acceptable levels of 25(OH)D, there is agreement that 25(OH)D levels less than 20 ng/mL indicate deficiency and a level more than 30 ng/mL is the median threshold needed to reduce fracture risk.

Calcium supplementation may be indicated if dietary intake is insufficient to achieve an intake of 1200 mg to 1500 mg daily. Although calcium supplementation should be recommended if necessary, total daily intake from food and supplements should not exceed 1500 mg daily, since the Women’s Health Initiative study (www.nhlbi.nih.gov/whi) demonstrated that an excess of calcium can lead to hypercalciuria and kidney stone formation.

Tables 3 and 4 specify daily recommended calcium intake and highlight common calcium food sources.

**TABLE 3. Recommended Daily Calcium Intake**

<table>
<thead>
<tr>
<th>Ages</th>
<th>Amounts (mg per day)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Birth – 6 months</td>
<td>210</td>
</tr>
<tr>
<td>7 months – 1 year</td>
<td>270</td>
</tr>
<tr>
<td>1 – 3 years</td>
<td>500</td>
</tr>
<tr>
<td>4 – 8 years</td>
<td>800</td>
</tr>
<tr>
<td>9 – 18 years</td>
<td>1300</td>
</tr>
<tr>
<td>19 – 30 years</td>
<td>1000</td>
</tr>
<tr>
<td>31 – 50 years</td>
<td>1000</td>
</tr>
<tr>
<td>51 – 70 years</td>
<td>1200</td>
</tr>
<tr>
<td>71+ years</td>
<td>1200</td>
</tr>
<tr>
<td>Pregnant and lactating</td>
<td>Same as for other women of comparable age</td>
</tr>
</tbody>
</table>


Only 35 percent of American adults consume the recommended daily allowance of calcium.
TABLE 4. Calcium Content of Common Foods

<table>
<thead>
<tr>
<th>Food</th>
<th>Mg Calcium per Serving</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yogurt, plain, fat free, 1 cup</td>
<td>450</td>
</tr>
<tr>
<td>American cheese, 2 oz.</td>
<td>348</td>
</tr>
<tr>
<td>Yogurt, fruit, 1 cup</td>
<td>315</td>
</tr>
<tr>
<td>Milk, fat free or low fat, 1 cup</td>
<td>300</td>
</tr>
<tr>
<td>Orange juice, calcium-fortified</td>
<td>300</td>
</tr>
<tr>
<td>Tofu, containing calcium sulfate, ½ cup</td>
<td>204</td>
</tr>
<tr>
<td>Macaroni and cheese, ½ cup</td>
<td>180</td>
</tr>
<tr>
<td>Collards, boiled, frozen, ½ cup</td>
<td>179</td>
</tr>
<tr>
<td>Pizza, cheese, 1 slice</td>
<td>111-147</td>
</tr>
<tr>
<td>Yogurt, frozen, fat free or low fat, ½ cup</td>
<td>105</td>
</tr>
<tr>
<td>Broccoli, cooked or fresh, 1 cup</td>
<td>90</td>
</tr>
<tr>
<td>Ice cream, ½ cup</td>
<td>84</td>
</tr>
</tbody>
</table>


There are various formulations of calcium available, most containing either calcium carbonate or calcium citrate. In a small study of 25 postmenopausal women, calcium citrate plus D was found to increase serum calcium and decrease serum PTH to a greater extent than did calcium carbonate plus D; both compounds were given with meals. When prescribing supplements, it is important to limit the dose at any one time to no greater than 500 to 600 mg because that is the maximum absorbed at any one time. Calcium carbonate supplements must be given with meals to optimize absorption; calcium citrate may be given with or without food. Additionally, calcium interferes with the absorption of iron, thyroid medications, and bisphosphonates; patients on those medications should be instructed to avoid taking them at the same time as the calcium. Table 5, below, highlights calcium levels in various supplements.

TABLE 5. Elemental Calcium in Supplements

<table>
<thead>
<tr>
<th>Product</th>
<th>Mg Elemental Calcium per pill/chew</th>
</tr>
</thead>
<tbody>
<tr>
<td>VIACTIV® chew or Os-Cal</td>
<td>500</td>
</tr>
<tr>
<td>TUMS® regular</td>
<td>200</td>
</tr>
<tr>
<td>TUMS Ultra</td>
<td>400</td>
</tr>
<tr>
<td>TUMS EX</td>
<td>300</td>
</tr>
<tr>
<td>Os-Cal+D</td>
<td>250</td>
</tr>
<tr>
<td>Citracal®</td>
<td>200</td>
</tr>
<tr>
<td>Citracal + D</td>
<td>315</td>
</tr>
</tbody>
</table>


Vitamin D - Vitamin D is necessary to enable calcium absorption. There are two natural sources of Vitamin D – food sources, and the manufacture of Vitamin D in the skin when exposed to ultraviolet radiation (sunlight). The liver and kidney then metabolize this Vitamin D to a bioavailable form. As the body ages, the skin is less able to manufacture Vitamin D, so that among the elderly, sunlight exposure affords
a negligible source, and compensatory hyperparathyroidism (with resultant bone resorption) can occur. Further, the increasing use of sunscreen has reduced the ultraviolet radiation available to the skin, so that Vitamin D deficiency is becoming more prevalent. Deficiency has been found to be especially prevalent among the elderly living at higher altitudes, those institutionalized, and those with hip fractures. In other countries, such as Saudi Arabia where cultural practices and lifestyle factors severely limit sun exposure among young females, the incidence of Vitamin D deficiency and resultant osteomalacia or osteopenia has been found to be very high. In a study of 321 Saudi women aged 31 years and older, severe Vitamin D deficiency was found in 52% of women.

Clinical trials have demonstrated that 800 IU (International Units) (20 µg) per day of Vitamin D in combination with 1200 mg calcium effectively reduces the risk of fractures in institutionalized patients. Furthermore, 400 IU (10 µg) Vitamin D per day in combination with 1000 mg calcium or 100,000 IU Vitamin D orally every fourth month without calcium reduces fracture risk in individuals more than 65 years of age living at home.

The current daily dietary reference intake for Vitamin D as published by the U.S. Department of Agriculture is 200 IU up to the age of 50, 400 IU for ages 50-70, and 600 IU for those older than 70 years of age. However, many professional associations believe that these levels of intake are not optimal and have published recommendations for additional Vitamin D intake. The North American Menopause Society recommends an intake of up to 800 IU/day for women at risk of deficiency because of inadequate sunlight exposure, such as elderly, chronically ill, housebound, and institutionalized women or those who live in Northern latitudes. The NOF recommends 800-1000 IU of Vitamin D₃ for adults age 50 and older; other recommendations can be found at their website, www.nof.org.

Supplementation with Vitamin D (also called calcitrol) is not without drawbacks. Studies have demonstrated that excess doses can lead to hypercalcemia and hypercalciuria. For this reason, routine supplementation in postmenopausal osteoporosis is not recommended, but should be reserved for those osteoporosis patients who have documented Vitamin D deficiency (via 25OHD measurement), steroid-induced osteoporosis, malabsorption syndromes, or who are otherwise deficient in Vitamin D.

In addition, when Vitamin D supplementation is considered, it should be noted that many multivitamin supplements contain Vitamin D₂ (ergocalciferol), which is from one third to one ninth as effective as Vitamin D₃ (cholecalciferol) in maintaining serum levels of 25(OH)D; thus, if a multivitamin contains 400 IU of Vitamin D₂, it is equivalent to taking 130 IU of Vitamin D₃.

According to the National Osteoporosis Risk Assessment (NORA) 2006 Physician Resurvey of 808 primary care physicians, 25(OH)D measurement is not a prevalent practice. Among those respondents, 75% “never” or “infrequently” order a serum 25(OH)D level for new female osteoporosis patients, and about 60% reported that they did not know the optimal level of 25(OH)D needed to optimize calcium absorption. However, two out of three physicians recommended Vitamin D to all of their postmenopausal patients. While current thought varies as to optimal serum levels of Vitamin D to effect fracture prevention, many clinicians consider levels below 30 ng/mL as indicative of deficiency.

**Sodium** - Avoidance of excess sodium is recommended, since there is a positive relationship between urinary sodium (reflecting excess sodium intake) and urinary calcium excretion. Results of two studies in adult women suggest that each additional gram of sodium eaten per day increases bone loss by one percent per year, unless the extra calcium lost in the urine is replaced by more calcium in the diet (Devine et al. 1995, Shorter et al. 1988).

**Alcohol** - Chronic alcoholism leads to lower BMD and higher fracture risk due to poor nutrition and malabsorption of nutrients, liver disease and resultant abnormal Vitamin D metabolism, direct toxicity to osteoblasts, and an increased propensity to fall. A prospective study of 85,000 middle aged women showed that those who consumed more than 25 g of alcohol daily had increased fracture risk compared to...
abstainers (25 g of alcohol is the equivalent of approximately 24 oz of beer, 7 oz of wine, or 3 oz of liquor). The same effect has been shown in men who drink more than 27 drinks per week, particularly in those who preferred beer over wine or other spirits. However, moderate alcohol consumption (7 oz. of alcohol for women and 14 oz. of alcohol for men per week) was associated with higher BMD in the Framingham heart study. However, until further study delineates the beneficial from detrimental effects of alcohol, multiple sources advise no more than two drinks daily, based on the findings above.

**Miscellaneous Nutrients** - Trace elements, such as fluoride, phytochemicals, and vitamins other than D, as well as caffeine and herbal botanicals, have from time to time been examined with regard to bone health. However, study findings have been contradictory and none of these substances are currently recommended for prevention or treatment of osteoporosis.

**Lifestyle**

Factors other than dietary intake are also amenable to change and are an important part of any osteoporosis prevention program at any age. The first of these factors is exercise.

**Exercise** - Since bone loss accompanies prolonged bed-rest and immobility,
there is a suggestion that exercise stimulates skeletal growth. The 2004 Report of the Surgeon General, *Bone Health and Osteoporosis*, clearly outlines the benefit of exercise with regard to bone health issues at every age. Additionally, a large number of cross-sectional studies of both genders and at all stages of life have shown that bone density depends on customary activity levels, although the studies do not indicate whether physical attributes determine activity levels (i.e., well-muscled persons perform weight-lifting) or vice versa (weight lifting causes persons to be well-muscled). Several observational studies (European Vertebral Osteoporosis Study, Study of Osteoporotic Fractures, and Tromsø study) of exercise and fracture risk have yielded conflicting results among men and women; therefore, randomized controlled studies have been used to determine the effect of exercise on bone. These studies have demonstrated a beneficial effect on bone density from impact and non-impact exercise; pre-pubertal girls, pre- and postmenopausal women, and men have shown positive effects. In one study, pre-pubertal girls showed a 10% increase in femoral neck bone density following exercise. Impact exercises also appear to have a beneficial effect on BMD at the femoral neck in postmenopausal women and possibly pre-menopausal women. There are no conclusions on the effect of non-impact exercise, however.

Other studies have shown a high drop-out rate with intensive exercise regimes, and some studies have found an increase in falls, so that the actual effect of exercise programs on fracture rates among older individuals appears to be small; the principal effect of such programs may be to maintain muscle strength.

For these reasons, exercise programs are recommended at all ages and should be actively encouraged. Young girls and teens benefit in particular from impact exercises such as jumping. Older adults should be encouraged in balance and muscle strengthening exercises, and in walking as an impact exercise. It should be remembered, however, that exercise alone is insufficient therapy for those at high fracture risk.

### Cigarette Smoking

There are a large number of studies on the deleterious effects of cigarette smoking on peak bone mass, but relatively few studies on the relationship between cigarette smoking and bone loss. The principal effects noted have been enhanced metabolic breakdown of exogenous estrogen, earlier menopause, and lower body weight. Further, although there is no difference in bone density of smokers and non-smokers at the age of 50, those women who smoked experienced a 2% decline in BMD for every 10-year increase in age, so that there was about a 6% difference between smokers and non-smokers by 80 years of age. There is also an independent effect of cigarette smoking on the risk of hip fracture.

Therefore cigarette smoking is discouraged at all ages to contribute towards optimal bone health as well as to afford accrual of other health benefits of smoking cessation.

### B. Primary Prevention

#### Goals

Whereas preventive efforts are intended for the universal population without defined risk factors, the goals of primary prevention are to increase or maintain bone mass and to prevent fracture in individuals at high risk for osteoporotic fracture. Individuals at high risk can be identified by virtue of risk factors as previously delineated in Table 2, page 11.

#### Approaches

##### Detection

One consideration that has been given much thought and attention in this group of individuals is defining the most appropriate (cost-effective and clinically sound) approach to BMD testing for detection of reduced bone mass. Currently, the gold standard is DXA. However, in rural and semi-rural locales, as well as in other clinical

---

**Exercise programs are recommended at all ages and should be actively encouraged.**

**Exercise alone is insufficient therapy for those at high fracture risk.**
situations (such as among nursing home residents who may not be able to be correctly positioned for DXA testing), other alternatives have been explored.

The authors of a report funded by the Agency for Healthcare Research and Quality (AHRQ) conducted a study to determine the most cost-effective approach to diagnosis in terms of hip fractures prevented. Results suggested that a sequential approach may be more cost-effective than DXA alone. The identified sequential approach was QUS of the heel followed by DXA of the femoral neck only for those with low values on QUS. QUS is less expensive and more widely available than DXA. There are no cut points that separate high risk from normal risk results,25 and it should be noted that if QUS results are indicative of low bone mass, a DXA is necessary to establish the appropriate diagnosis.

The optimal time to conduct testing has been a matter of some study. The U.S. Preventive Services Task Force (USPSTF) has recommended that BMD testing be carried out for postmenopausal women who have attained the age of 65 without other risk factors, and for postmenopausal women age 60 to 64 at high risk with other risk factors, including weight less than 70 kg., no current estrogen use, smoking, weight loss, family history, decreased physical activity, alcohol or caffeine use, or low calcium and Vitamin D intake.37 The NOF also recommends testing women age 65 and older and identifies common risk factors to justify testing in younger postmenopausal women:

- Family history of fragility fracture in a first degree relative
- Personal history of fracture as an adult
- Current cigarette smoking
- Body weight less than 127 pounds
- Use of oral corticosteroid therapy for more than three months

The Foundation also recommends testing for men with fractures or those on GnRH agonists for prostate cancer, as well as for all individuals with primary hyperparathyroidism.41

The goals of primary prevention are to increase or maintain bone mass and to prevent fracture in individuals at high risk for osteoporotic fracture.
COMMUNITY STAGED SCREENING PROGRAM

Lehigh Valley Hospital and Health Network (LVHHN) is a not-for-profit academic community hospital in Pennsylvania, with more than 50 specialties across three campuses. The osteoporosis outreach program began as a community education initiative solely with lectures. Through those lectures and a separate hip fracture study, it was found that few people were having DXAs or even being screened. Through a grant and philanthropy funds, two heel scanners were purchased.

No-charge community screenings were initiated, targeting individuals between 40 and 60 years of age. Within 12 months, 1048 individuals (9.8% male) were screened using an ultrasound heel bone density scanner. Screening results indicated T-scores at a level of -1.5 or less for 147 individuals. Letters were sent to each of these patient's primary care physicians requesting that they order a DXA.

Fifty-four patients, or 37% of the 147 patients with T-scores of -1.5 or less, actually obtained a DXA scan. When asked, participants not obtaining a DXA stated they did not think that finding out if they had osteoporosis was important because if so, their primary care physicians would have ordered the test.

RESULTS

Osteopenia was diagnosed on DXA in 24% of patients (n=13) that underwent DXA, and almost half the patients, or 26, met the criteria for osteoporosis. In total, 72% of patients who had a DXA suggested by low T-score on heel ultrasound were diagnosed with some form of low bone mass.

<table>
<thead>
<tr>
<th>DXA Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>No or non-significant bone loss 17%</td>
</tr>
<tr>
<td>Results unavailable 11%</td>
</tr>
<tr>
<td>Osteopenia 24%</td>
</tr>
<tr>
<td>Osteoporosis 48%</td>
</tr>
</tbody>
</table>

Introduction to Measure 01 – Screening, Females at Risk

The approach regarding whom to screen is one that must be individualized for each patient; it is a recommendation best made by balancing a patient’s individual history and presence of risk factors. Identification of some risk factors (such as long-term oral glucocorticoid administration) is relatively simple, but diligence is needed to identify some of the most common risk factors among postmenopausal women. For example, weighing patients is a routine matter in many physician offices, but recognition of low body weight (below 127 pounds) as a risk factor possibly indicating the need for screening for osteoporosis requires vigilance on the part of providers. Similarly, including questions about parental history of hip fracture or osteoporosis, and recognizing certain long-term medications (e.g., anti-seizure medications) as risk factors requires heightened awareness beyond the “routine” nature of taking a family or medication history.

This measure is intended for use in care settings exclusive of the acute inpatient hospital stay or emergency department encounter, and seeks to ensure that postmenopausal women are appropriately identified for BMD testing.
**Performance Measure Profile**

PERFORMANCE MEASURE Osteoporosis 01 - Screening, females at risk

Osteoporosis screening for females at risk

**DELIVERY SETTINGS**
- Ambulatory Care
- Subacute Care
- Long Term Care
- Home Health
- Rehabilitation Facility and Inpatient Rehabilitation Facility

**NUMERATOR STATEMENT**
Patients age 60-64 with one or more risk factors and patients age 65 and over who have had at least one documented central dual-energy X-ray absorptiometry (DXA) scan performed. If DXA is not available and documented as such, then any other FDA-approved fracture risk assessment method may be used (quantitative computed tomography [QCT], quantitative ultrasound [QUS], radiographic absorptiometry [RA], single-energy X-ray absorptiometry [SXAI], peripheral DXA [pDXA]).

**DENOMINATOR STATEMENT**
Females age 60 and over

**EXCLUSIONS:**
- Patients with “comfort measures only”
- Patients for whom DXA scanning contraindicated as documented by a physician/advanced practice nurse/physician assistant (physician/APN/PA)
- Patients with a current diagnosis of osteoporosis
- Patients who refuse DXA scanning
- Patients on pharmacotherapy for osteoporosis
- Patients in a clinical trial pertaining to osteoporosis

**DEFINITIONS:**
Risk factors include any one or more of the following: amyloidosis, ankylosing spondylitis, chronic obstructive pulmonary disease, congenital porphyria, Cushing’s syndrome, eating disorders (e.g., anorexia nervosa), female athlete triad, gastrectomy, Gaucher disease, hemochromatosis, hemophilia, hyperparathyroidism, hypogonadism, primary and secondary (e.g., amenorrhea), hypophosphatasia, Idiopathic scoliosis, inflammatory bowel disease, Insulin-dependent diabetes mellitus, lymphoma and leukemia, malabsorption syndromes, mastocytosis, multiple myeloma, multiple sclerosis, pernicious anemia, rheumatoid arthritis, severe liver disease, especially primary biliary cirrhosis, spinal cord transsection, sprue, stroke (CVA), thalassemia, thyrotoxicosis, tumor secretion of PTH-related peptide, weight loss, dialysis, or medications known to accelerate bone loss, which include aluminum, anticonvulsants (phenobarbital, phenytoin), aromatase inhibitors, cytotoxic drugs, glucocorticosteroids and adrenocorticotropic, Gonadotropin-releasing hormone agonists, immunosuppressants, long-term heparin use, proton pump inhibitors (PPIs), progesterone (parenteral, long-acting), supraphysiologic thyroxine doses, Tamoxifen (premenopausal use), total parenteral nutrition.

Osteoporosis = Diagnosis Code 733.0, vertebral fracture, or hip fracture

Pharmacotherapy = FDA-approved agents, exclusive of calcium and Vitamin D.

Documented = DXA test results in clinical record.
The evidence for the most appropriate intervals for repeat testing is sparse and the topic controversial; this is an area needing further research and additional evidence to support cost-effective approaches. AHRQ notes that, in a funded study of the effectiveness of various strategies for diagnosing and monitoring postmenopausal osteoporosis, repeat BMD results were not used to alter therapy. The NOF and others recommend interval testing to monitor results of osteoporosis therapy every year or two. Optimal interval monitoring of patients at-risk by virtue of other disease processes has not been well-delineated. However, the American Association of Clinical Endocrinologists recommends that repeat BMD testing should be done at varying intervals as follows:

- “Normal” baseline BMD – consider follow-up measurement every three to five years
- If on osteoporosis prevention program – follow-up measurement every one to two years
- If on a therapeutic program – follow-up measurement yearly for two years; if stable, every two years thereafter. If unstable, annual measurement until stable bone mass achieved, then every two years.

Primary versus Secondary Osteoporosis

At the initial diagnosis of osteoporosis, additional testing is recommended to search for and identify underlying causes since there are many other factors and underlying disorders that can cause bone loss. Again, there is controversy as to the most cost-effective approach to additional testing. Diverse recommendations for testing to eliminate underlying causes of osteoporosis are detailed in Table 6, although as the AHRQ discerns, “there is no evidence on which to base a testing strategy, … but the most frequently ordered tests were thyrotropin or thyroid-stimulating hormone (TSH), complete blood cell count (CBC), and chemistry profiles.”
TABLE 6. Testing to Rule Out Secondary Osteoporosis

<table>
<thead>
<tr>
<th>Source</th>
<th>Guideline</th>
</tr>
</thead>
</table>
| American Association of Clinical Endocrinologists (AACE)<sup>a</sup> | Women with postmenopausal osteoporosis:  
  - Complete history and physical  
  - Complete blood cell count (CBC)  
  - Serum chemistry studies (especially, calcium, phosphorus, protein, albumin, liver enzymes, alkaline phosphatase, creatinine, electrolytes), urinary calcium excretion  
  - If secondary cause suggested, other studies as per text |
| American College of Obstetricians and Gynecologists (ACOG)<sup>b</sup> |  
  - First Tier: Serum calcium, chemistry analysis, 24-hour urine calcium and creatinine, PTH levels, TSH level if on thyroid replacement  
  - Second Tier: Renal profile, Vitamin D and PTH levels, thyroid panel, protein electrophoresis (to look for myeloma) |
| Institute for Clinical Systems Improvement (ICSI)<sup>c</sup> | Minimum: Screening lab profile  
  Consider if no prior workup: Renal and hepatic profiles, calcium, alkaline phosphatase, phosphorus, CBC, sedimentation rate, or C-reactive protein, TSH and thyroxine, 24 hour urinary calcium, PTH, 25-OH Vitamin D.  
  - If indicated, testosterone in men, estradiol in women, tissue transglutaminase, 24-hour free cortisol or dexamethasone suppression, serum and urine protein electrophoresis. |


Once a causative factor for secondary osteoporosis has been identified, it is important to treat the underlying cause since the therapeutic response can be substantial. For example, large increases in bone mass have been observed after treatment of hyperparathyroidism, and studies have shown that fracture rates decrease substantially when glucocorticoid therapy is discontinued.<sup>37</sup>
**Introduction to Measure 02 - Secondary Causes**

There is considerable debate in the medical community concerning which tests should be conducted to identify any underlying disease states as a cause of osteoporosis, and no single battery of tests has been deemed better than another. This measure is intended to ensure a minimal laboratory data set, the results of which, if abnormal, can lead to further testing as warranted. It is, of course, possible to obtain additional initial tests, but the laboratory evaluations presented here represent the most economical approach that can “point the way” to any further tests that may be required. Each clinician, given these test results and individual patient information, can tailor further investigation as warranted.

**Performance Measure Profile**

**PERFORMANCE MEASURE Osteoporosis 02 - Secondary Causes**

Laboratory investigation for secondary causes of osteoporosis.

**DELIVERY SETTINGS**

- Hospital Inpatient
- Emergency Department
- Subacute Care
- Ambulatory Care
- Long Term Care
- Rehabilitation Facility and Inpatient Rehabilitation Facility

**NUMERATOR STATEMENT**

Patients who have had appropriate minimal laboratory investigation ordered or performed prior to discharge or within three months of initial osteoporosis diagnosis.

**DENOMINATOR STATEMENT**

Patients with a new diagnosis of osteoporosis.

**EXCLUSIONS:**

- Patients with “comfort measures only”
- Patients who have had the same laboratory tests in the 12 months prior to the diagnosis of osteoporosis
- Patients with a known underlying disorder as the cause of osteoporosis, as documented by a physician/advanced practice nurse/physician assistant (physician/APN/PA)
- Patients who refuse laboratory tests
- Patients in a clinical trial pertaining to osteoporosis

**DEFINITIONS:**

Appropriate minimal laboratory investigation = a complete blood cell count (CBC), chemistry panel to include renal and hepatic function, serum calcium, and a 25(OH)D level.

Osteoporosis = Diagnosis Code 733.0, vertebral fracture, or hip fracture

**SELECTED REFERENCES:**

Glucocorticoid Therapy

Persons taking glucocorticoids are at particularly high risk of developing osteoporosis secondary to medication administration, and glucocorticoids are the most common cause of secondary osteoporosis. Glucocorticoids alter bone metabolism such that bone formation is reduced and resorption is increased, leading to rapid bone loss after initiation of therapy. A 1996 study (Buckley, et al43) demonstrated the effectiveness of calcium and Vitamin D supplementation in preventing bone loss in the lumbar spine and greater trochanter in rheumatoid arthritis patients taking low-dose, long-term glucocorticoid therapy. Bone loss is highest in the initial months of treatment.

Current ACR recommendations regarding glucocorticoid-induced osteoporosis44 include

- Modification of other risk factors, such as smoking and alcohol
- Instruction in weight-bearing exercise
- For those beginning therapy with a prednisone equivalent of >5 mg daily for planned duration of more than three months:
  - Calcium and Vitamin D supplementation
  - Bisphosphonates
- For those receiving long-term prednisone equivalent of >5 mg daily, above measures plus:
  - Treatment to replace sex hormones if deficient or otherwise indicated
  - BMD testing
    - If BMD -1 or worse, prescribe bisphosphonates, consider calcitonin as second line
    - If BMD normal, follow-up and repeat BMD either annually or biannually

Introduction to Measure 03 – BMD Testing, Glucocorticoid Patients

When the Osteoporosis Technical Advisory Panel initially drafted this measure, hospital inpatients, emergency department patients, and patients in subacute care were included. Recognizing, however, the sheer volume of patients likely to have glucocorticoid administration and the likelihood that duration of therapy would not be known, the panel subsequently removed patients in those care settings from the settings for whose patients the measure is intended. However, should a patient in one of those settings be recognized as having been on long-term oral glucocorticoid therapy (longer than three months), steps should be taken to ensure that bone mineral density (BMD) is assessed, if not previously done.

Further, there has been some differentiation in the medical community as to what daily or cumulative dose poses a threat to the bone health of the patient. Essentially, any patient on oral glucocorticoids for more than three months is likely to be consuming doses sufficiently damaging to bone to pose a threat to skeletal health. Therefore there are no dosage thresholds given for this measure. The ACR is expected to issue new guidelines on this topic, and of note, are the recent daily dosage levels for which Medicare qualifies BMD testing for reimbursement have been lowered to 5 mg.

The decision as to which patients to treat for low bone density is one best made on an individual basis for each patient, although many sources recommend pharmaceutical intervention for those patients whose T-score is -1 or lower. It should be noted that the only current medications approved for osteoporosis prevention are alendronate and risedronate.
Since the effects of inhaled corticosteroids on bone are still uncertain, this measure was formulated to address only those individuals on oral steroid medication.

Performance Measure Profile

PERFORMANCE MEASURE Osteoporosis 03 - BMD testing, glucocorticoid patients
Bone mineral density (BMD) testing for those at high risk of fracture due to glucocorticoid administration.

DELIVERY SETTINGS
- Ambulatory Care
- Long Term Care
- Home Health
- Rehabilitation Facility and Inpatient Rehabilitation Facility

NUMERATOR STATEMENT
Patients who have had a central dual-energy X-ray absorptiometry (DXA) of the spine and hip ordered or performed since initiation of glucocorticoid therapy.

DENOMINATOR STATEMENT
Patients age 18 and over on oral glucocorticoid therapy for three months or longer.

EXCLUSIONS:
- Patients with “comfort measures only”
- Patients on FDA-approved osteoporosis medication other than calcium and Vitamin D
- Patients who refuse DXA testing
- Patients in a clinical trial pertaining to osteoporosis.

SELECTED REFERENCES:
Dietary and Lifestyle

As discussed earlier, adequate dietary intake of calcium and Vitamin D must be maintained, with supplementation as necessary. Cigarette smoking should cease and alcohol consumption limited to no more than two drinks daily.

Introduction to Measure 04 – Dietary Education, Osteoporosis

Ideally, dietary education as to appropriate levels of intake of calcium and Vitamin D, as well as the natural sources for those nutrients, should begin early in life as such education will foster development of good lifetime habits. Certainly, once low bone mass has been detected, this education is imperative. However, since there is no convenient way to identify patients who have low bone mass that has not yet progressed to osteoporotic levels (also referred to as osteopenia), this measure was developed for the patient population that can be identified with diagnostic codes reflecting either osteoporosis, hip fracture, or vertebral fracture. If electronic health records can be searched retrospectively by a “key word” search function (osteopenia), or if clinical processes allow “flagging” of records or BMD reports that report osteopenia, then this measure could be exercised for the osteopenic population as well. Note also that patients who sustain any type of fracture, not solely those with hip or vertebral fracture, can realize substantial benefit from education regarding calcium and Vitamin D intake.

During measure development, consideration was given to specifying the level of intake to which patients should be educated. However, it is recognized that each patient may or may not need supplementation at varying levels, dependent upon his or her natural food intake, sunlight exposure, and measurement of Vitamin D levels in the blood via 25(OH)D measurement. Collating those varying sets of information would complicate record review to the point where the burden of retrieving information would be unacceptable. Given the current prevalent lack of nutritional education, it was determined that documented discussion of these nutritional elements would represent advancement in care.

Compliance with this measure may be easily achieved by use of pre-printed materials and documentation of the discussion and provision of materials in the clinical record. There are also internet sources for calculation of calcium intake, such as that available at www.iofbonehealth.org.
Performance Measure Profile

PERFORMANCE MEASURE Osteoporosis 04 - Dietary Education, Osteoporosis
Dietary education for patients with osteoporosis.

DELIVERY SETTINGS
- Ambulatory Care
- Subacute Care
- Long Term Care
- Home Health
- Rehabilitation Facility and Inpatient Rehabilitation Facility

NUMERATOR STATEMENT
Patients, or the caregivers of such patients, who have received education regarding calcium and Vitamin D intake within the most recent 12 months.

DENOMINATOR STATEMENT
Patients with a diagnosis of osteoporosis.

EXCLUSIONS:
- Patients with “comfort measures only”
- Patients and their caregivers who refuse dietary counseling
- Patients in a clinical trial pertaining to osteoporosis

DEFINITIONS:
Osteoporosis = Diagnosis Code 733.0, vertebral fracture, or hip fracture

SELECTED REFERENCES:
Exercise

Regular muscle-strengthening and balance exercises should be encouraged. These programs are beneficial principally by improving balance and gait imbalance, and specialized programs for balance improvement are now being developed. In some references, Tai Chi has been cited as beneficial for improvement in overall balance. In some studies, weight-bearing exercises have been shown to have benefit in building bone as well. Caution is advised, however, in initiating any exercise program for those with low bone mass since, in some instances, improper exercise techniques are more detrimental than helpful. An initial short course of instruction and supervision by a physical therapy professional to enable appropriate exercise techniques may be useful.

Introduction to Measure 05 – Activity Counseling, Osteoporosis

As discussed in the previous measure regarding dietary concepts, healthy exercise habits should begin at an early age and specialized instruction for patients with osteopenia should occur. However, this measure focuses on the outpatient and long-term care population with a diagnosis of osteoporosis, hip fracture, or vertebral fracture and acknowledges that exercise instruction needs to be frequently reinforced.

Further, depending on the individual's clinical condition, fall prevention education may need to be instituted (see page 46 for a discussion on approaches to fall prevention).

PERFORMANCE MEASURE OSTEOPOROSIS 05 - ACTIVITY EDUCATION, OSTEOPOROSIS

Activity Education for osteoporosis patients

DELIVERY SETTINGS
- Ambulatory Care
- Subacute Care
- Long Term Care
- Home Health
- Rehabilitation Facility and Inpatient Rehabilitation Facility

NUMERATOR STATEMENT
Patients who have received documented activity education appropriate to their age and condition or a referral for activity counseling within the most recent 36 months.

DENOMINATOR STATEMENT
Patients with osteoporosis

EXCLUSIONS:
- Patients with “comfort measures only”
- Patients for whom exercise is contraindicated as documented by a physician/advanced practice nurse/physician assistant (physician/APN/PA) or physical rehabilitation professional
- Patients who refuse exercise instruction
- Patients with dementia
- Patients in a clinical trial pertaining to osteoporosis

DEFINITIONS:
Osteoporosis = Diagnosis Code 733.0, vertebral fracture, or hip fracture
Pharmacotherapy

Who Should Be Treated?

Determining which patients should be treated with pharmaceuticals remains an evolving concept, and research is continuing to define the optimal, cost-effective approach most appropriate for patients with various clinical presentations. The WHO is expected to release an evidence-based 10-year fracture risk model, whereby treatment interventions can be based on risk assessment as determined by that model. The algorithm enhances the current T-score definition of osteoporosis and is intended to be applicable to the patient who has never been treated for osteoporosis. The risk score is thought to be calculated on several risk factors in addition to the femoral neck T-score and calculation of the fracture risk probability score is then intended to provide a basis for deciding when to intervene. Since the WHO development group is working in secrecy, full details of the algorithm will not be known until publication. Until publication of the model, however, the decision to treat with pharmaceutical agents, in addition to calcium and Vitamin D, remains a decision to be made between patient and physician on an individual basis, supported by recommendations from various sources (see box on next page). 41, 42, 45

SELECTED REFERENCES:

WHICH PATIENTS SHOULD HAVE PHARMACOTHERAPY?

**National Osteoporosis Foundation**
Initiate therapy to reduce fracture risk in women with:
- BMD T-scores below -2.0 by hip DXA with no risk factors
- BMD T-scores below -1.5 by hip DXA with one or more risk factors
- A prior vertebral or hip fracture

**North American Menopause Society**
Initiate therapy for post-menopausal females with:
- An osteoporotic vertebral fracture
- BMD equal to or less than -2.5
- BMD equal to or less than -2.0 and one of the following risk factors:
  - Weight less than 127 lbs or low BMI
  - Fragility fracture since menopause
  - History of parental hip fracture

**American Association of Clinical Endocrinologists**
The following women may benefit from pharmacologic treatment of osteoporosis:
- Women with postmenopausal osteoporosis
- Women with low-trauma fractures (also known as fragility fractures) and low BMD
- Women with BMD T-scores of -2.5 and below
- Women with borderline-low BMD (T-scores of -1.5 and below) if risk factors are present
- Women in whom nonpharmacologic preventive measures are ineffective (bone loss continues or low-trauma fractures [also known as fragility fractures] occur)

Consider the following additional measures in specific circumstances:
- Pharmacologic agents (in addition to calcium and Vitamin D) to prevent bone loss in perimenopausal and postmenopausal women at high risk of developing osteoporosis
- A bisphosphonate (alendronate or risedronate) for all adult women who will require more than 7.5 mg of prednisone or its equivalent for more than three weeks.

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Introduction to Measure 06 – Pharmacotherapy

Elsewhere in this monograph and in other measures, it is acknowledged that a viable optional approach to some fragility fracture patients is placement on U.S. Food and Drug Administration-approved pharmacotherapy without antecedent BMD testing. This measure, as opposed to those developed for the acute fracture patient, targets patients in longer-term care settings and as outpatients to identify which, over a period of time, are still receiving appropriate pharmacotherapy once an osteoporosis diagnosis has been established. Again, some clinicians may have elected to treat low bone mass or fracture patients in advance of an osteoporosis diagnosis as preventive or presumptive treatment. This measure does not focus on those patients but rather on patients with an established diagnosis of osteoporosis.

In addition, some clinicians may, for clinically valid reasons, elect to discontinue pharmacotherapy temporarily or permanently. If the rationale for the discontinuance is documented, it is also acceptable.
While calcium and Vitamin D are certainly indicated for such patients, those components alone are insufficient therapy for osteoporosis, and exercise of this measure at frequent intervals followed by inquiry of those patients who do not take their prescription medication may help counter the high rates of medication non-compliance that have been reported in the professional literature and discussed further in Section C, Secondary Prevention (page 38).
Pharmacologic Options

FDA-approved pharmacologic options for the prevention and/or treatment of postmenopausal osteoporosis include, in alphabetical order: bisphosphonates (alendronate, alendronate plus D, ibandronate and risedronate or risedronate with 500 mg of calcium as the carbonate), calcitonin, estrogens (estrogen and/or hormone therapy), parathyroid hormone (PTH [1-34], teriparatide), and selective estrogen receptor modulators (SERMs) (raloxifene). All agents except for PTH are antiresorptive agents; they act by decreasing osteoclastic activity, thus reducing bone turnover. Readers should consult full prescribing information for additional details.

Bisphosphonates

Alendronate
Brand name: Fosamax® or Fosamax® plus D
Alendronate sodium is approved by the FDA for the prevention (5 mg daily and 35 mg weekly) and treatment (10 mg daily and 70 mg weekly, or 70 mg weekly with either 2800 IU or 5600 IU of Vitamin D3) of osteoporosis in postmenopausal women. Alendronate reduces the incidence of spine, hip and wrist fractures by about 50% over three years in patients with a prior spine fracture. It reduces the incidence of spine fractures by 48% over three years in patients without a prior spine fracture.

Ibandronate
Brand name: Boniva®
Ibandronate sodium, in a once monthly tablet of 150 mg, is approved by the FDA for the prevention and treatment of postmenopausal osteoporosis. Ibandronate reduces the incidence of spine fractures by about 50% over three years.

Risedronate
Brand name: Actonel® or Actonel® with Calcium
Risedronate sodium (5 mg daily dose, and 35 mg weekly dose, or 75 mg on two successive days monthly, or 35 mg weekly dose with six tablets of 500 mg calcium carbonate each) is approved by the FDA for the prevention and treatment of postmenopausal osteoporosis. Risedronate reduces the incidence of spine fractures by 41% to 49% and non-spine fractures by 36% over three years in patients with a prior spine fracture.

Zoledronic Acid

Brand name: Reclast®
On May 3, 2007, the New England Journal of Medicine published both an article and editorial concerning the HORIZON Pivotal Fracture Trial. In this double-blind, placebo-controlled, multi-national trial, more than 7,000 patients received either a placebo or an annual infusion of 5 mg zoledronic acid. Conducted over a three year period, there was a 70% reduction in the risk of morphometric vertebral fracture and a 41% reduction in the risk of hip fracture. Vertebral fractures, clinical fractures, and clinical vertebral fractures were reduced by 25%, 33%, and 77%, respectively. Although adverse events were similar in the two study groups, serious atrial fibrillation occurred more frequently in the zoledronic acid group.

Compliance with oral antiresorptive medication regimes has been notoriously problematic. Approved on August 17, 2007, for treatment of osteoporosis, the medication must be given at “infusion centers” rather than doctors’ offices. This intravenous approach may offer an attractive alternative that may increase compliance with prescription therapy for some unable to tolerate oral therapy.

Side Effects - Side effects are similar for all bisphosphonate medications and include gastrointestinal problems, such as difficulty swallowing, inflammation of the esophagus, and gastric ulcer. Alendronate and risedronate must be taken on an empty stomach, first thing in the morning, with 8 oz of water (no other liquid), at least 30 minutes before eating or drinking. Patients should remain upright (sitting or standing) during this interval as well. Ibandronate should be taken on the same day each month, at least 60 minutes before first food, drink (other than water), or medication of the day. Ibandronate must be taken on an empty stomach, first thing in the morning, with a glass of tap water. Patients must remain upright for at least one hour after taking medication.

There have been a few reports of osteonecrosis of the jaw (ONJ) (particularly following intravenous bisphosphonate treatment) and of visual disturbances, which should be reported to the health care provider as soon as possible. The reports of development of ONJ associated with the administration of bisphosphonates have appeared recently in professional publications and in the popular press.\textsuperscript{11, 46-52} ONJ is a condition wherein the maxillary or mandibular bone is exposed, usually following invasive dental procedures such as tooth extraction or implant insertion; the exposed bone is painful and difficult to heal. The vast majority of cases have occurred in patients who have received intravenous bisphosphonates such as Zometa or Aredia for the treatment of cancer complications, but about 5% of cases have occurred in patients taking oral bisphosphonates for osteoporosis or Paget's disease treatment.\textsuperscript{49} In May of 2005, manufacturers sent letters to dental professionals to alert them to ONJ occurrences, particularly among cancer patients, and the package insert for intravenous forms of bisphosphonates was revised.\textsuperscript{53}

Since the incidence of ONJ cases is quite low, most experts feel that the risks of not taking the drug far outweigh the risk of developing ONJ. The American Society for Bone and Mineral Research (ASBMR), in a July 17, 2006, editorial,\textsuperscript{52} recommends, among other considerations:
- A dental examination before or soon after initiating oral bisphosphonates
- Completion of invasive dental work before or soon after initiating oral bisphosphonates
- Informing patients of the low risk of ONJ
- Instructing patients taking oral bisphosphonates to inform their dental practitioner of taking these meds
- Maintenance of good oral hygiene practices (exams, fillings, etc.)
- Limiting dental surgery to that minimally necessary

There is agreement that additional research is needed to further identify the etiology and optimal management of ONJ.

Since bisphosphonates have not been available for a prolonged period of time, the effects of long-term administration are unknown. There has been interest among clinicians regarding scattered reports that patients on Alendronate for five years or more may safely be given a “drug holiday” for periods of up to five years without adverse effect. A recent report in \textit{JAMA} explores the results of stopping Alendronate after five years of treatment, concluding that for many women, discontinuation of alendronate for up to five years does not appear to significantly increase fracture risk, but that women at very high risk of clinical vertebral fractures may benefit by continuing beyond five years.\textsuperscript{54}

Calcitonin
Brand name: \textit{Miacalcin\textsuperscript{R}}, \textit{Calcimar\textsuperscript{R}}, or \textit{Fortical\textsuperscript{R}}
Salmon calcitonin is FDA-approved for the treatment of osteoporosis in women who are at least five years postmenopausal. It is delivered as a single daily intranasal spray that provides 200 IU of the drug. Subcutaneous administration by injection also is available. The effect of nasal calcitonin on fracture risk is not stated in the prescribing information. Calcitonin is generally considered safe although some patients experience rhinitis and, rarely, epistaxis.
**Estrogen/Hormone Therapy**

(Estrogen therapy brand names: e.g., Climara®, Estrace®, Estraderm®, Estratab®, Ogen®, Ortho-Est®, Premarin®, Vivelle®) (Hormone therapy brand names: e.g., Activella™, Femhrt®, Premphase®, Prempro®)

Estrogen/hormone therapy ET/HT is approved by the FDA for the prevention of osteoporosis, and relief of vasomotor symptoms and vulvovaginal atrophy associated with menopause. Women who have not had a hysterectomy may require HT, which contains progestin to protect the uterine lining. The Woman’s Health Initiative (WHI) found that five years of HT (Prempro®) reduced the risk of clinical vertebral fractures and hip fractures by 34% and other osteoporotic fractures by 23%. However, the FDA recommends that when ET/HT use is considered solely for prevention of osteoporosis, approved non-estrogen treatments should first be carefully considered. The WHI reported increased risks of myocardial infarction, stroke, invasive breast cancer, pulmonary emboli, and deep vein phlebitis during five years of treatment with Prempro. Other doses and combinations of estrogen and progestins were not studied and, in the absence of comparable data, their risks should be assumed to be comparable. Because of the risks, ET/HT should be used in the lowest possible doses for the shortest duration to meet treatment goals.

**Selective Estrogen Receptor Modulators**

**Raloxifene**

Brand name: Evista®

Raloxifene, a selective estrogen receptor modulator (SERM), is approved by the FDA for both prevention and treatment of osteoporosis in postmenopausal women. Raloxifene reduces the risk of spine fracture by 30% in patients with and by 55% in patients without a prior spine fracture, over three years. Raloxifene has been shown to reduce the risk of estrogen receptor positive breast cancer.

Raloxifene increases the risk of deep vein thrombosis to a degree similar to that observed with estrogen. It also increases hot flashes (6% more than placebo).

Combination therapy (usually a bisphosphonate with a non-bisphosphonate) can provide additional small increases in BMD when compared with monotherapy; however, the impact of combination therapy on fracture rates is unknown. The added cost and potential side effects should be weighed against potential gains.

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**THE STAR TRIAL**

The Study of Tamoxifen and Raloxifene, or STAR trial, showed that raloxifene works as well as tamoxifen in reducing breast cancer risk for postmenopausal women at increased risk of the disease. In STAR, both drugs reduced the risk of developing invasive breast cancer by about 50 percent. In addition, within the study, women who were prospectively and randomly assigned to take raloxifene daily, and who were followed for an average of about four years, had 36% fewer uterine cancers and 29% fewer blood clots than the women who were assigned to take tamoxifen.

STAR enrolled 19,747 postmenopausal women who were at increased risk of breast cancer. Participants were randomly assigned to receive either 60 mg of raloxifene (Evista) or 20 mg of tamoxifen (Nolvadex®) daily for five years. The trial was coordinated by the National Surgical Adjuvant Breast and Bowel Project (NSABP), a network of cancer research professionals, and is sponsored by the National Cancer Institute, part of the National Institutes of Health.

Women taking either drug had equivalent numbers of strokes, heart attacks, and bone fractures. Both raloxifene and tamoxifen are known to protect bone health; it is estimated that half a million postmenopausal women are currently taking raloxifene by prescription to prevent or treat osteoporosis.

**Parathyroid hormone [teriparatide, rhPT(1-34)]**

Brand name: *Forteo®*

Teriparatide is approved by the FDA for the treatment of osteoporosis in postmenopausal women at high risk for fracture; it is an anabolic (bone-building) agent when administered by daily subcutaneous injection. Teriparatide in a dose of 20 µg daily was shown to decrease the risk of spine fractures by 65% and non-spine fractures by 53% in patients with osteoporosis, after an average of 18 months of therapy. (After 18 months, teriparatide therapy was found to have caused thickening of the outer shell of bones, large increases in connections between bony islands within the skeleton, and an overall net increase in bone strength.)³⁷

Teriparatide is well tolerated, although some patients experience leg cramps and dizziness. Because teriparatide caused an increase in the incidence of osteosarcoma in rats, patients with an increased risk of osteosarcoma (e.g., patients with Paget’s disease of bone, prior radiation therapy of the skeleton, bone metastases, hypercalcemia, or a history of skeletal malignancy) should not receive teriparatide therapy. The safety and efficacy of teriparatide has not been demonstrated beyond two years of treatment.⁴¹

Note that the agents approved for prevention of osteoporosis are Alendronate, Ibandronate, Risedronate, ET/HT after other non-estrogen therapy considered, and Raloxifene.

**C. Secondary Prevention**

Secondary prevention occurs through a series of interventions after a fragility fracture has occurred. It is this population of patients for whom several targeted interventions have been recognized, since fragility fracture, particularly in postmenopausal women and older men, presumes the existence of low bone mass. It has also been shown that patients with fragility fracture often are not tested or treated for osteoporosis, and there is a significant opportunity for improvement in management of these patients (see Table 7).
<table>
<thead>
<tr>
<th>Author/Year</th>
<th>Design</th>
<th>Subjects</th>
<th>Results</th>
<th>Number Treated</th>
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<tbody>
<tr>
<td>Freedman²/2000</td>
<td>Review claims database from 3,000,000 patients</td>
<td>Women &gt;55 with radial fracture</td>
<td>22.9% received treatment</td>
<td>1162</td>
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<td>Gehlbach³/2000</td>
<td>Review 954 chest X-rays in hospitalized women</td>
<td>Women &gt;60 with vertebral fracture</td>
<td>50% fracture incidence; 18% received treatment</td>
<td>132</td>
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<tr>
<td>Andrade⁴/2003</td>
<td>HMO database review</td>
<td>Women &gt;60 with hip, vertebral, or radial fracture</td>
<td>24% received treatment within 12 months</td>
<td>3492</td>
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<tr>
<td>Neuner⁵/2003</td>
<td>Retrospective cohort of primary care practices</td>
<td>Patients with vertebral fracture</td>
<td>32% received treatment</td>
<td>206</td>
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<tr>
<td>Eisman⁶/2004</td>
<td>Survey of 69,358 postmenopausal women in Australia</td>
<td>Postmenopausal women with fracture</td>
<td>28% received treatment</td>
<td>20,113</td>
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<td>Kim⁷/2004</td>
<td>100 chest X-rays in emergency department</td>
<td>Patients &gt;60 with moderate to severe fracture</td>
<td>55% incidence</td>
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</tr>
<tr>
<td>Kroth⁸/2004</td>
<td>Retrospective review of academic internal medicine clinic</td>
<td>Women &gt;40 with vertebral fracture on chest X-ray</td>
<td>50% received treatment</td>
<td>113</td>
</tr>
<tr>
<td>Papaionnou⁹/2004</td>
<td>Literature review in Canada</td>
<td>Adults &gt;40 with fragility fracture</td>
<td>5.2% to 37.5% received treatment</td>
<td></td>
</tr>
<tr>
<td>Gardner¹⁰/2005</td>
<td>Randomized trial of providing information</td>
<td>Patients with hip fracture</td>
<td>19% in control group, 42% in study group received treatment</td>
<td>80</td>
</tr>
</tbody>
</table>

Continued on next page
Fragility fracture is defined as a fracture occurring as a result of a fall from standing height or less, or as a result of low-impact trauma. Frequently, these fractures are sustained at the vertebra, hip, distal radius, and humerus, with other body sites sustaining fracture less frequently. Fragility fractures are the complication of osteoporosis, and the occurrence of a fragility fracture is a risk factor for additional fractures to occur. Lindsay et al.,55 in 2001, reviewed data from four large, 3-year osteoporosis treatment trials conducted at 373 study centers in North America, Europe, Australia, and New Zealand between 1993 and 1998. Among the 2,725 postmenopausal women studied, those with one or more vertebral fracture(s) at the initiation of the study were at five-fold risk of sustaining another vertebral fracture within the following year as compared with those women without vertebral fracture at the start of the study.
Vertebral fracture is often not recognized due to lack of standardization of the definition of vertebral fracture, and when found incidentally on a PA or lateral chest X-ray is not often recognized as a harbinger of osteoporosis. The most frequent indication of vertebral fracture is the patient's observation of a sense of height loss (more difficult to reach upper shelves, etc.) or reporting that her clothes are longer. For this reason, it is recommended that accurate height measurements should be recorded for all patients after the age of 50, using a stadiometer if possible. Current readings should be compared to those previous or, if a patient is new to the practice, their remembered peak height. If there is a loss of two inches or greater, a vertebral fracture assessment (VFA) should be completed.

The goals of secondary prevention are to preserve or build bone mass, prevent additional fracture, and to reduce fracture pain and restore the level of function extant prior to the current fracture. It is beyond the scope of this monograph to review acute fracture care and rehabilitative considerations in entirety; the reader is directed to orthopedic and rehabilitative disciplines for specific fracture treatment approaches and recommendations. However, early intervention in the course of treatment for fragility fracture in order to address underlying osteoporosis is advocated. This intervention begins, in more than one instance, with emergency department treatment, continues through any inpatient care, and spans the continuum of care through rehabilitative services, home care, and ambulatory care venues, as evidenced by previous measures applicable in those environments.

For purposes of care improvement, the measures in this monograph designed to address care after fractures do not distinguish between fragility fracture and other traumatic fracture, since patients with low bone mass will more easily sustain fracture than those without low bone mass, given the same trauma, and since the incidence of undetected low bone mass in these patients is relatively high. It is vitally important to exercise every diagnostic/treatment approach for all fracture patients.

Introduction to Measures 07 and 08 – Risk Assessment/Treatment after Fracture

These two measures are designed to address the patient population that has sustained a fracture. Given the abundant opportunity outlined in the text for improvement of care for these patients, the two measures have been formulated to work in a complementary fashion: one is for care at the time of fracture; the other for longer-term subsequent care. Measure 07, for acute care patients, specifies either a DXA prescription for DXA, or pharmacotherapy prior to hospital discharge. Measure 08 for subsequent care is designed to identify those patients who “fall through the cracks” – the patients who have prescriptions for care upon discharge from the acute environment but never obtain the needed imaging or medication. It may also identify those instances in which there has been less than optimal communication among different providers to ensure necessary care.
Performance Measure Profile

PERFORMANCE MEASURE  Osteoporosis 07 - Risk Assessment/Treatment After Fracture, Acute Care
Patients age 50 or over with a fracture who have either a dual-energy X-ray absorptiometry (DXA) scan ordered or performed or a prescription for FDA-approved pharmacotherapy for osteoporosis prior to discharge. If DXA is not available and documented as such, then any other FDA-approved testing method may be used (quantitative computed tomography [QCT], quantitative ultrasound [QUS], radiographic absorptiometry [RA], single-energy X-ray absorptiometry [SX]), peripheral DXA [pDXA]).

DELIVERY SETTINGS
- Hospital Inpatient
- Emergency Department

NUMERATOR STATEMENT
Patients who have had either a central DXA ordered or performed or a prescription for pharmacotherapy for osteoporosis prevention or treatment prior to discharge. If DXA is not available and documented as such, then any other FDA-approved fracture risk assessment method may be used (QCT, QUS, RA, SX, peripheral DXA [pDXA]).

DENOMINATOR STATEMENT
Patients age 50 or over with a fracture.

Exclusions:
- Patients with “comfort measures only”
- Patients with a fracture of the finger, toe, facial bone(s) or skull
- Patients on osteoporosis medication prior to fragility fracture
- Patients who have had a DXA scan in the 12 months prior to the fracture
- Patients for whom DXA scan and pharmacotherapy are both contraindicated as documented by a physician/advanced practice nurse/physician assistant (physician/APN/PA)
- Patients who refuse both DXA scan and pharmacotherapy
- Patients in a clinical trial pertaining to osteoporosis

DEFINITIONS:
Pharmacotherapy = FDA-approved agents, exclusive of calcium and Vitamin D.

SELECTED REFERENCES:
**Performance Measure Profile**

**PERFORMANCE MEASURE: Osteoporosis 08 - Risk Assessment/Treatment after Fracture, Non-Acute Care**

Patients age 50 or over with fracture who have either a dual-energy X-ray absorptiometry (DXA) scan ordered or performed or a prescription for FDA-approved pharmacotherapy for osteoporosis within three months of the date of recognition of the fracture. If DXA is not available and documented as such, then any other FDA-approved fracture risk assessment method may be used (quantitative computed tomography [QCT], quantitative ultrasound [QUS], radiographic absorptiometry [RA], single-energy x-ray absorptiometry [SXA], peripheral DXA [pDXA]).

**DELIVERY SETTINGS**
- Ambulatory Care
- Subacute Care
- Long Term Care
- Home Health
- Rehabilitation Facility and Inpatient Rehabilitation Facility

**NUMERATOR STATEMENT**

Patients who have had either a central DXA ordered or performed or a prescription for pharmacotherapy for osteoporosis prevention or treatment within three months of the date of fracture. If DXA is not available and documented as such, then any other FDA-approved fracture risk assessment method may be used (quantitative computed tomography [QCT], quantitative ultrasound [QUS], radiographic absorptiometry [RA], single-energy x-ray absorptiometry [SXA], peripheral DXA [pDXA]).

**DENOMINATOR STATEMENT**

Patients age 50 or over with a fracture.

**Exclusions:**
- Patients with “comfort measures only”
- Patients with a fracture of the finger, toe, facial bone(s) or skull
- Patients on osteoporosis medication
- Patients who have had a DXA scan in the 12 months prior to the fracture
- Patients for whom DXA scan and pharmacotherapy are both contraindicated as documented by a physician/advanced practice nurse/physician assistant (physician/APN/PA)
- Patients not seen within 3 months of the date of fracture
- Patients who refuse both DXA scan and pharmacotherapy
- Patients in a clinical trial pertaining to osteoporosis

**DEFINITIONS:**

Pharmacotherapy = FDA-approved agents, exclusive of calcium and Vitamin D.

**SELECTED REFERENCES:**
- U. S. Preventive Services Task Force (USPSTF). Screening for Osteoporosis in Postmenopausal Women.
Specific provisions related to treatment of low bone mass underlying fragility fracture mimic, in many instances, those measures advocated for primary prevention, but with a greater degree of urgency and direction.

**Pharmacotherapy**

Unfortunately, all too often the first considerations of diagnosis of and pharmacotherapy for osteoporosis occur at the time of fracture, rather than at an earlier time of risk and low bone mass. Numerous studies have demonstrated that a low percentage of patients with fragility fractures receive treatment for osteoporosis, as detailed previously in Table 7, page 39. It is thought that this low treatment rate is a result of failure to detect low bone mass rather than failure to prescribe treatment once low bone mass has been determined by BMD. Often, attention is focused on the fracture itself rather than the underlying disease process. Increased diligence is needed in addressing low bone mass in such clinical presentations by either performance of a bone density test, referral for a bone density test or to an osteoporosis specialist/service after the acute fracture phase has stabilized, or placement on pharmacotherapy for osteoporosis if the clinical situation warrants. The NOF recommends treatment of women with hip or vertebral fracture without precedent bone density testing.41 Measure 06, page 34, attests to the necessity of continuing pharmacotherapy and encouraging compliance from the patient.

**HOSPITAL ASSESSMENT FOR OSTEOPOROSIS AFTER FRACTURE**

At a large Midwestern teaching hospital, an osteoporosis fracture intervention program was developed whereby 165 patients hospitalized with a fragility (minimal trauma) fracture participated in an intervention program; 38 other patients received routine osteoporosis education. The intervention program included assessment of risk factors, patient education, and maintenance of records by a nurse practitioner and a peripheral bone density test, as well as an osteoporosis consultation, evaluation, and recommendations for treatment by a multidisciplinary team of physicians prior to discharge. (As originally constructed, only education was done by nurse practitioners with a letter to the primary care physician for follow-up after discharge, but this approach produced no changes in care.)

At the 6-month follow-up, 67% of hip fracture patients and 48% of non-hip fracture patients in the intervention group were taking antiresorptive medications, whereas the rates prior to intervention had been 28% and 5.6%, respectively. Among the 38 patients with routine osteoporosis care and education, there was no change from baseline rates of treatment.


**Dietary Education**

As in preventive phases, adequate dietary intake of calcium and Vitamin D must be maintained, with supplementation as necessary. Instruction must be given to the patient and/or caregiver to ensure adequate understanding of dietary requirements.

**Smoking/Alcohol Education**

Since there is a direct toxic effect of cigarette smoke and alcohol on bone mass, as previously described, there is an imperative need to address these issues with patients. Patients should stop cigarette smoking and limit alcohol consumption to no more than two drinks daily.
Introduction to Measure 09 - Smoking/Alcohol Education

This measure, designed for all care settings, is aimed at ensuring that populations of fracture patients age 50 or more and osteoporosis patients receive education, prior to discharge and at least on an annual basis, that cigarette smoking and alcohol consumption are deleterious to bone health. The instructions should be given to all patients, whether or not they admit to cigarette smoking and alcohol consumption. Ideally, as with some previous measures, this education would have begun in the teenage years and the current effort would represent reinforcement of principles already familiar to the patient.

Performance Measure Profile

PERFORMANCE MEASURE Osteoporosis 09 - Smoking/Alcohol Education
Smoking and Alcohol Education for osteoporosis and fracture patients

DELIVERY SETTINGS
- Hospital Inpatient
- Emergency Department
- Ambulatory Care
- Subacute Care
- Long Term Care
  - Home Health
  - Rehabilitation Facility and Inpatient Rehabilitation Facility

NUMERATOR STATEMENT
Patients who have had documented education prior to discharge or in the most recent 12 months regarding cigarette smoking cessation and excess alcohol consumption

DENOMINATOR STATEMENT
Osteoporosis patients of any age and patients with a fracture age 50 and over.

EXCLUSIONS:
- Patients with “comfort measures only”
- Patients not seen in the previous 12 months
- Patients with dementia
- Patients in a clinical trial pertaining to osteoporosis

DEFINITIONS:
Osteoporosis = Diagnosis Code 733.0, vertebral fracture, or hip fracture

SELECTED REFERENCES:
Fall Prevention

Persons with osteoporosis are particularly prone to hip fracture after a fall.

- More than one third of adults 65 and older fall each year\(^{56, 57}\).
- Of those who fall, 20% to 30% suffer moderate to severe injuries that make it hard to get around or live alone and increase the chance of early death\(^{58}\).
- The total direct cost of all fall injuries for people 65 and older in 2000 was slightly more than $19 billion: $0.2 billion ($179 million) for fatal falls and $19 billion for nonfatal falls\(^{59}\).
- In 2000, fractures were both the most common and most costly type of nonfatal fall injuries. More than one third of nonfatal injuries were fractures, but they made up 61% of costs – or $12 billion\(^{59}\).
- Hip fractures are the most frequent broken bones from falls\(^{60}\).
- From 1993 to 2003, the number of hip fracture hospitalizations increased by 19%, from 261,000 to 309,500\(^{61}\).
- By 2020, the annual direct and indirect cost of fall injuries is expected to reach $43.8 billion (in current dollars)\(^{62}\).

Depending on the individual’s clinical condition, fall prevention education may be indicated. Results of research into the effectiveness of fall prevention strategies have been mixed\(^{62-65}\), with evidence suggesting that fall prevention education is only effective if targeted for those who have had more than one fall and/or have balance or gait difficulties. However, it is difficult to justify not educating a patient prone to fracture as to interventions that might prevent that fracture from occurring, given the social, economic, and humanistic impact that can result from a fall.

Fall prevention education may be accomplished by various methods – home safety instruction sheets or pamphlets, verbal education with a “checklist” format, video presentations, and other suitable methods. However, all methods must incorporate the essentials of fall prevention in the home and outside environment, which include

- Adequate lighting, particularly in areas where elevations differ, such as stairways and thresholds
- Elimination of clutter and loose throw rugs
- Elimination of extension cords and other tripping hazards
- Availability of “grab bars” and other assistive devices in bathing areas
- Adequate footwear to allow stable traction on all walking surfaces

There are other falling hazards. Small children and pets are occasional sources of tripping and falling, and visual impairments should be corrected as much as possible. Family members, as well as patients, need to be educated regarding fall prevention concepts to ensure continual reinforcement.

Sample patient safety checklists are readily available from many publications and internet sources.
Introduction to Measure 10 – Fall Risk and Personal Safety Education

As outlined in the text, fall prevention education is important education for many patients, including the elderly, infirmed, low bone mass populations, and those visually impaired. This measure is targeted to those with osteoporosis or those older than age 50 with a fracture. On occasion, pharmaceutical companies will have standardized safety checklists, or physical therapy professionals will be able to supply or formulate these items along with professional association websites, such as www.nof.org.

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Performance Measure Profile

PERFORMANCE MEASURE Osteoporosis 10 - Fall Risk and Personal Safety Education

Fall Risk and personal safety education

DELIVERY SETTINGS

- Ambulatory Care
- Subacute Care
- Long Term Care
- Home Health
- Rehabilitation Facility and Inpatient Rehabilitation Facility

NUMERATOR STATEMENT

Patients, or their caregivers, who have received documented fall risk and personal safety education to minimize risk of future falls within three months of new diagnosis or date of fracture.

DENOMINATOR STATEMENT

Patients 50 and older with new osteoporosis or fracture diagnosis.

EXCLUSIONS:

- Patients in a clinical trial pertaining to osteoporosis

DEFINITIONS:

Fall risk and personal safety education = discussion to eliminate fall and trip hazards OR provision of a home safety checklist OR distribution of written educational material.

Osteoporosis = Diagnosis Code 733.0, vertebral fracture, or hip fracture

SELECTED REFERENCES:

Similarly, a review of the patient’s medication regime may reveal use of medications or combinations of medications that render the patient more prone to falling by causing dizziness or light-headedness. Frequent medication reviews with the primary care physician or geriatrician, including review of use of over-the-counter medications, should be conducted to identify any potential for falls, with dosage adjustments as warranted. The goal of this review should be to maximize overall health and functional benefits of the medications while minimizing their adverse effects, such as falls. Classes of medications often associated with increasing the risk of falls include psychotrophic medications. Other medications with a strong link to an increased risk of falling include serotonin-reuptake inhibitors, tricyclic antidepressants, neuroleptic agents, benzodiazepines, anticonvulsants, and class IA antiarrhythmic medications.

**Exercise**

Finally, as discussed previously, exercises such as Tai Chi and individualized instruction may be helpful. Regular muscle-strengthening and balance exercises should be encouraged, and a formalized program of exercise instruction by a physical therapist may be indicated. Supervision of exercise programs prescribed for those with osteoporosis may be warranted, since care must be taken to avoid further strain and injury occasioned by improper exercise techniques.
PART II. SUMMARY OF RECOMMENDED MEASURES

Section 1. Osteoporosis Measures by Setting

A. Hospital Inpatient and Emergency Department
   Secondary Causes
   Risk Assessment/Treatment After Fracture, Acute Care
   Smoking/Alcohol Education

B. Ambulatory Care, Rehabilitation and Inpatient Rehabilitation Facility, Long Term Care, Home Health
   Screening, Females at Risk
   Secondary Causes
   BMD Testing, Glucocorticoid Patients
   Dietary Education, Osteoporosis
   Activity Education, Osteoporosis
   Pharmacotherapy
   Risk Assessment/Treatment After Fracture, Non-Acute Care
   Smoking/Alcohol Education
   Fall Risk Education

C. Subacute Care
   Screening, Females at Risk
   Secondary Causes
   Dietary Education, Osteoporosis
   Activity Education, Osteoporosis
   Pharmacotherapy
   Risk Assessment/Treatment After Fracture, Non-Acute Care
   Smoking/Alcohol Education
   Fall Risk Education
**Performance Measure Profile**

**PERFORMANCE MEASURE Osteoporosis 01 - Screening, females at risk**

Osteoporosis screening for females at risk

**DELIVERY SETTINGS**

- Ambulatory Care
- Subacute Care
- Long Term Care
- Home Health
- Rehabilitation Facility and Inpatient Rehabilitation Facility

**NUMERATOR STATEMENT**

Patients age 60-64 with one or more risk factors and patients age 65 and over who have had at least one documented central dual-energy X-ray absorptiometry (DXA) scan performed. If DXA is not available and documented as such, then any other FDA-approved fracture risk assessment method may be used (quantitative computed tomography [QCT], quantitative ultrasound [QUS], radiographic absorptiometry [RA], single-energy X-ray absorptiometry [SX]), peripheral DXA [pDXA]).

**DENOMINATOR STATEMENT**

Females age 60 and over

**EXCLUSIONS:**

- Patients with “comfort measures only”
- Patients for whom DXA scanning contraindicated as documented by a physician/advanced practice nurse/physician assistant (physician/APN/PA)
- Patients with a current diagnosis of osteoporosis
- Patients who refuse DXA scanning
- Patients on pharmacotherapy for osteoporosis
- Patients in a clinical trial pertaining to osteoporosis

**DEFINITIONS:**

Risk factors include any one or more of the following: amyloidosis, ankylosing spondylitis, chronic obstructive pulmonary disease, congenital porphyria, Cushing’s syndrome, eating disorders (e.g., anorexia nervosa), female athlete triad, gastrectomy, Gaucher disease, hemochromatosis, hemophilia, hyperparathyroidism, hypogonadism, primary and secondary (e.g., amenorrhea), hypophosphatasia, Idiopathic scoliosis, inflammatory bowel disease, Insulin-dependent diabetes mellitus, lymphoma and leukemia, malabsorption syndromes, mastocytosis, multiple myeloma, multiple sclerosis, pernicious anemia, rheumatoid arthritis, severe liver disease, especially primary biliary cirrhosis, spinal cord transsection, sprue, stroke (CVA), thalassemia, thyrotoxicosis, tumor secretion of PTH-related peptide, weight loss, dialysis, or medications known to accelerate bone loss, which include aluminum, anticonvulsants (phenobarbital, phenytoin), aromatase inhibitors, cytotoxic drugs, glucocorticosteroids and adrenocorticotropic, Gonadotropin-releasing hormone agonists, immunosuppressants, long-term heparin use, proton pump inhibitors (PPIs), progesterone (parenteral, long-acting), supraphysiologic thyroxine doses, Tamoxifen (premenopausal use), total parenteral nutrition.

Osteoporosis = Diagnosis Code 733.0, vertebral fracture, or hip fracture

Pharmacotherapy = FDA-approved agents, exclusive of calcium and Vitamin D.

Documented = DXA test results in clinical record.
SELECTED REFERENCES:


Performance Measure Profile

PERFORMANCE MEASURE Osteoporosis 02 - Secondary Causes
Laboratory investigation for secondary causes of osteoporosis.

DELIVERY SETTINGS
- Hospital Inpatient
- Emergency Department
- Subacute Care
- Ambulatory Care
- Long Term Care
- Rehabilitation Facility and Inpatient Rehabilitation Facility

NUMERATOR STATEMENT
Patients who have had appropriate minimal laboratory investigation ordered or performed prior to discharge or within three months of initial osteoporosis diagnosis.

DENOMINATOR STATEMENT
Patients with a new diagnosis of osteoporosis.

EXCLUSIONS:
- Patients with “comfort measures only”
- Patients who have had the same laboratory tests in the 12 months prior to the diagnosis of osteoporosis
- Patients with a known underlying disorder as the cause of osteoporosis, as documented by a physician/advanced practice nurse/physician assistant (physician/APN/PA)
- Patients who refuse laboratory tests
- Patients in a clinical trial pertaining to osteoporosis

DEFINITIONS:
Appropriate minimal laboratory investigation = a complete blood cell count (CBC), chemistry panel to include renal and hepatic function, serum calcium, and a 25(OH)D level.
Osteoporosis = Diagnosis Code 733.0, vertebral fracture, or hip fracture

SELECTED REFERENCES:
Performance Measure Profile

PERFORMANCE MEASURE Osteoporosis 03 - BMD testing, glucocorticoid patients
Bone mineral density (BMD) testing for those at high risk of fracture due to glucocorticoid administration.

DELIVERY SETTINGS
- Ambulatory Care
- Long Term Care
- Home Health
- Rehabilitation Facility and Inpatient Rehabilitation Facility

NUMERATOR STATEMENT
Patients who have had a central dual-energy X-ray absorptiometry (DXA) of the spine and hip ordered or performed since initiation of glucocorticoid therapy.

DENOMINATOR STATEMENT
Patients age 18 and over on oral glucocorticoid therapy for three months or longer.

EXCLUSIONS:
- Patients with “comfort measures only”
- Patients on FDA-approved osteoporosis medication other than calcium and Vitamin D
- Patients who refuse DXA testing
- Patients in a clinical trial pertaining to osteoporosis.

SELECTED REFERENCES:
**Performance Measure Profile**

**PERFORMANCE MEASURE  Osteoporosis 04 - Dietary Education, Osteoporosis**
Dietary education for patients with osteoporosis.

**DELIVERY SETTINGS**
- Ambulatory Care
- Subacute Care
- Long Term Care
- Home Health
- Rehabilitation Facility and Inpatient Rehabilitation Facility

**NUMERATOR STATEMENT**
Patients, or the caregivers of such patients, who have received education regarding calcium and Vitamin D intake within the most recent 12 months.

**DENOMINATOR STATEMENT**
Patients with a diagnosis of osteoporosis.

**EXCLUSIONS:**
- Patients with “comfort measures only”
- Patients and their caregivers who refuse dietary counseling
- Patients in a clinical trial pertaining to osteoporosis

**DEFINITIONS:**
Osteoporosis = Diagnosis Code 733.0, vertebral fracture, or hip fracture

**SELECTED REFERENCES:**
Performance Measure Profile

PERFORMANCE MEASURE OSTEOPOORIS 05 - ACTIVITY EDUCATION, OSTEOPOORIS
Activity Education for osteoporosis patients

DELIVERY SETTINGS
- Ambulatory Care
- Subacute Care
- Long Term Care
- Home Health
- Rehabilitation Facility and Inpatient Rehabilitation Facility

NUMERATOR STATEMENT
Patients who have received documented activity education appropriate to their age and condition or a referral for activity counseling within the most recent 36 months.

DENOMINATOR STATEMENT
Patients with osteoporosis

EXCLUSIONS:
- Patients with “comfort measures only”
- Patients for whom exercise is contraindicated as documented by a physician/advanced practice nurse/physician assistant (physician/APN/PA) or physical rehabilitation professional
- Patients who refuse exercise instruction
- Patients with dementia
- Patients in a clinical trial pertaining to osteoporosis

DEFINITIONS:
Osteoporosis = Diagnosis Code 733.0, vertebral fracture, or hip fracture

SELECTED REFERENCES:
**Performance Measure Profile**

**PERFORMANCE MEASURE**  Osteoporosis 06 - Pharmacotherapy
Pharmacotherapy for osteoporosis

**DELIVERY SETTINGS**
- Ambulatory Care
- Subacute Care
- Long Term Care
- Home Health
- Rehabilitation Facility and Inpatient Rehabilitation Facility

**NUMERATOR STATEMENT**
Patients who have had pharmacotherapy for osteoporosis prescribed within the most recent 12 months.

**DENOMINATOR STATEMENT**
Patients age 50 or older with a diagnosis of osteoporosis.

**EXCLUSIONS:**
- Patients with “comfort measures only”
- Patients for whom pharmacotherapy is contraindicated or is not being prescribed for another reason as documented by a physician/advanced practice nurse/physician assistant (physician/APN/PA) or clinical pharmacist
- Patients with metastatic fracture
- Patients who refuse pharmacotherapy
- Patients in a clinical trial pertaining to osteoporosis

**DEFINITIONS:**
Pharmacotherapy for osteoporosis = Any FDA-approved medication for the treatment of osteoporosis, excluding calcium and Vitamin D.
Osteoporosis = Diagnosis Code 733.0, vertebral fracture, or hip fracture

**SELECTED REFERENCES:**
**Performance Measure Profile**

**PERFORMANCE MEASURE**  Osteoporosis 07 - Risk Assessment/Treatment After Fracture, Acute Care

Patients age 50 or over with a fracture who have either a dual-energy X-ray absorptiometry (DXA) scan ordered or performed or a prescription for FDA-approved pharmacotherapy for osteoporosis prior to discharge. If DXA is not available and documented as such, then any other FDA-approved testing method may be used (quantitative computed tomography [QCT], quantitative ultrasound [QUS], radiographic absorptiometry [RA], single-energy X-ray absorptiometry [SXA], peripheral DXA [pDXA]).

**DELIVERY SETTINGS**
- Hospital Inpatient
- Emergency Department

**NUMERATOR STATEMENT**
Patients who have had either a central DXA ordered or performed or a prescription for pharmacotherapy for osteoporosis prevention or treatment prior to discharge. If DXA is not available and documented as such, then any other FDA-approved fracture risk assessment method may be used (QCT, QUS, RA, SXA, peripheral DXA [pDXA]).

**DENOMINATOR STATEMENT**
Patients age 50 or over with a fracture.

Exclusions:
- Patients with “comfort measures only”
- Patients with a fracture of the finger, toe, facial bone(s) or skull
- Patients on osteoporosis medication prior to fragility fracture
- Patients who have had a DXA scan in the 12 months prior to the fracture
- Patients for whom DXA scan and pharmacotherapy are both contraindicated as documented by a physician/advanced practice nurse/physician assistant (physician/APN/PA)
- Patients who refuse both DXA scan and pharmacotherapy
- Patients in a clinical trial pertaining to osteoporosis

**DEFINITIONS:**
Pharmacotherapy = FDA-approved agents, exclusive of calcium and Vitamin D.

**SELECTED REFERENCES:**
Performance Measure Profile

PERFORMANCE MEASURE: Osteoporosis 08 - Risk Assessment/Treatment after Fracture, Non-Acute Care

Patients age 50 or over with fracture who have either a dual-energy X-ray absorptiometry (DXA) scan ordered or performed or a prescription for FDA-approved pharmacotherapy for osteoporosis within three months of the date of recognition of the fracture. If DXA is not available and documented as such, then any other FDA-approved fracture risk assessment method may be used (quantitative computed tomography [QCT], quantitative ultrasound [QUS], radiographic absorptiometry [RA], single-energy x-ray absorptiometry [SX], peripheral DXA [pDXA]).

DELIVERY SETTINGS
- Ambulatory Care
- Subacute Care
- Long Term Care
- Home Health
- Rehabilitation Facility and Inpatient Rehabilitation Facility

NUMERATOR STATEMENT
Patients who have had either a central DXA ordered or performed or a prescription for pharmacotherapy for osteoporosis prevention or treatment within three months of the date of fracture. If DXA is not available and documented as such, then any other FDA-approved fracture risk assessment method may be used (quantitative computed tomography [QCT], quantitative ultrasound [QUS], radiographic absorptiometry [RA], single-energy x-ray absorptiometry [SX], peripheral DXA [pDXA]).

DENOMINATOR STATEMENT
Patients age 50 or over with a fracture.

Exclusions:
- Patients with “comfort measures only”
- Patients with a fracture of the finger, toe, facial bone(s) or skull
- Patients on osteoporosis medication
- Patients who have had a DXA scan in the 12 months prior to the fracture
- Patients for whom DXA scan and pharmacotherapy are both contraindicated as documented by a physician/advanced practice nurse/physician assistant (physician/APN/PA)
- Patients not seen within 3 months of the date of fracture
- Patients who refuse both DXA scan and pharmacotherapy
- Patients in a clinical trial pertaining to osteoporosis

DEFINITIONS:
Pharmacotherapy = FDA-approved agents, exclusive of calcium and Vitamin D.

SELECTED REFERENCES:

• U. S. Preventive Services Task Force (USPSTF). Screening for Osteoporosis in Postmenopausal Women.

Performance Measure Profile

PERFORMANCE MEASURE  Osteoporosis 09 -Smoking/Alcohol Education
Smoking and Alcohol Education for osteoporosis and fracture patients

DELIVERY SETTINGS
- Hospital Inpatient
- Emergency Department
- Ambulatory Care
- Subacute Care

LONG TERM CARE
Home Health
Rehabilitation Facility and Inpatient Rehabilitation Facility

NUMERATOR STATEMENT
Patients who have had documented education prior to discharge or in the most recent 12 months regarding cigarette smoking cessation and excess alcohol consumption

DENOMINATOR STATEMENT
Osteoporosis patients of any age and patients with a fracture age 50 and over.

EXCLUSIONS:
- Patients with “comfort measures only”
- Patients not seen in the previous 12 months
- Patients with dementia
- Patients in a clinical trial pertaining to osteoporosis

DEFINITIONS:
Osteoporosis = Diagnosis Code 733.0, vertebral fracture, or hip fracture

SELECTED REFERENCES:
**Performance Measure Profile**

**PERFORMANCE MEASURE Osteoporosis 10 - Fall Risk and Personal Safety Education**
Fall Risk and personal safety education

**DELIVERY SETTINGS**
- Ambulatory Care
- Subacute Care
- Long Term Care
- Home Health
- Rehabilitation Facility and Inpatient Rehabilitation Facility

**NUMERATOR STATEMENT**
Patients, or their caregivers, who have received documented fall risk and personal safety education to minimize risk of future falls within three months of new diagnosis or date of fracture.

**DENOMINATOR STATEMENT**
Patients 50 and older with new osteoporosis or fracture diagnosis.

**EXCLUSIONS:**
- Patients in a clinical trial pertaining to osteoporosis

**DEFINITIONS:**
Fall risk and personal safety education = discussion to eliminate fall and trip hazards OR provision of a home safety checklist OR distribution of written educational material.

Osteoporosis = Diagnosis Code 733.0, vertebral fracture, or hip fracture

**SELECTED REFERENCES:**
PART III. SELF STUDY QUESTIONS

SELF STUDY QUESTIONS

The following scenarios are intended to reinforce your understanding and application of the clinical concepts contained in this monograph.

1. You are a primary care physician in Phoenix, Arizona, and are seeing Mrs. Adams, a 70-year-old Caucasian female new to your practice. She has just relocated from Buffalo, New York. She has not brought her medical records with her, but she reports that she was never tested for osteoporosis. The most appropriate test to order to diagnose osteoporosis is:
   a. QUS of the heel and wrist
   b. DXA of the hip and spine
   c. MRI of the hip
   d. PA and lateral chest X-ray for vertebral fracture
   e. None; obtain prior medical records

2. Mrs. Adams has had BMD results indicative of osteoporosis. In order to best assess her for calcium deficiency, you would:
   a. Take a dietary history from the patient with special attention to dairy consumption
   b. Order a urinary calcium
   c. Order a serum calcium
   d. Order a 25(OH)D level

3. Mrs. Adams is severely deficient in calcium. You want to be sure her intake is adequate and you counsel her for increasing her intake of foods that are calcium-rich. Of the food sources below, the richest food source for calcium is:
   a. 1 cup fat free milk
   b. 1 cup fat free yogurt
   c. 1 cup calcium-fortified orange juice
   d. 1 cup broccoli

4. Mrs. Adams’ current medications include hydrochlorothiazide 25 mg PO daily, lisinopril 5 mg PO daily, and a daily multivitamin for seniors (contains 200 mg calcium and 400 IU of Vitamin D). She states that she used to be 5’5” in her 30s-40s. Her current height is 5’2” and weight is 122 lbs. She states that she does not routinely have dairy intake in her diet. Which of the following calcium and Vitamin D therapies would be most appropriate for this patient?
   a. 500 mg calcium + 200 IU Vitamin D once daily with breakfast
   b. 500 mg calcium + 200 IU Vitamin D twice daily with meals
   c. 500 mg calcium + 400 IU Vitamin D three times daily with meals
   d. No additional calcium or Vitamin D necessary

5. Since Mrs. Adams has BMD results indicating osteoporosis, you also want to place her on FDA-approved pharmacotherapy. The agent of first choice, shown to be most effective in reducing the risk of vertebral, non-vertebral, and hip fracture, is:
   a. Risedronate
   b. Ibandronate
   c. Alendronate
d. Vitamin D and calcium supplementation

6. Mrs. Adams has a history of breast cancer six years prior; she had a mastectomy, chemotherapy, and a first course of radiation, followed two years later by a second course of chemotherapy and radiation to the spine. Which of the following would you never add to your first choice:
   a. Calcitonin
   b. Raloxifene
   c. Teriparatide
   d. All of the above

7. The primary mechanism of action of antiresorptive agents is:
   a. Regulation of PTH levels
   b. Increase in osteoblastic activity
   c. Decrease in osteoclastic activity
   d. b. and c.
   e. All the above

8. You see Mrs. Adams six months after you prescribe pharmacotherapy and suspect that she is not taking her prescribed medication. You would like to monitor her progress in terms of improved bone density. The best way to do this is:
   a. Repeat BMD testing
   b. Order bone turnover markers
   c. Have her bring all her current medication containers to the next office visit in six weeks
   d. Order a serum calcium

9. One of the other patients in your practice, Mr. Johnson, an 82-year-old with osteopenia. He also has a number of other risk factors for fracture. Which of the following of Mr. Johnson's other risk factors is most predictive of a future fracture?
   a. Calcium level 9.1
   b. 25(OH) Vitamin D 25ng/mL
   c. Active osteoarthritis
   d. History of a prior low energy vertebral fracture
   e. High level of bone turnover (N-telopeptide)

10. Mr. Johnson’s wife, 80 years old, received a chest x-ray during flu season for a possible pneumonia where a wedge deformity of T8 was found on the lateral view. The most appropriate next step would be:
    a. Follow the deformity with serial radiographs
    b. Order a radionuclide bone scan
    c. Order a DXA test
    d. Begin a bisphosphonate drug
    e. Obtain an orthopedic consult for possible kyphoplasty

11. Ada Brown, who is 60 years old, tells you during her annual exam that just after she saw you last year she fell on a wet floor at the supermarket and broke her wrist. What would you do?
    a. Order a DXA of wrist
    b. Order a DXA of spine and hip
    c. Order bone markers
    d. Tell her that she had a fall associated with significant trauma and no further workup is needed
12. One of the younger patients in your practice is Amy, who is 17 years old. She has had asthma since early childhood, for which she has used a variety of oral medications and rescue inhalers. She has been anorexic since the age of 14 and she is 5'4", weighing 101 pounds. You decide to order a DXA scan, based on her medication history, nutritional history, and current BMI. Which reference range should be used in reporting her DXA results?
   a. Z-score
   b. T-score
   c. % calcific density
   d. None of the above
   e. All of the above

13. Mrs. Jones is an active 76 year-old patient who lives with her husband in their own home. Mrs. Jones enjoys going to the senior center for bingo, trips, and socializing. At a community health fair, she was screened for osteoporosis. Her heel ultrasound results were -2.6. You should:
   a. Order a DXA to confirm the diagnosis
   b. Repeat the ultrasound at the hospital
   c. Place her on a bisphosphonate without further testing
   d. Ignore the result – everybody's result is low when they are elderly and she appears to be healthy.
PART IV. QUALITY IMPROVEMENT IN OSTEOPOROSIS MANAGEMENT

Section I. Measurement Is Key to Improvement

“The only way to know whether the quality of care is improving is to measure performance” according to the Institute of Medicine (Performance Measurement: Accelerating Improvement, 2006).66

By its nature, measurement is comparative and used to establish relationships based on common units of analysis.67 For example, during the start-up phase of an improvement initiative, measurement allows staff to establish the baseline performance of a process or activity, to assess current practice, and to identify opportunities for improvement. Over time, continued measurement helps staff compare current performance against baseline data to evaluate the success of their interventions.

In addition to improving clinical outcomes, two important reasons to measure performance in health care organizations are to assess change for QI purposes within an organization (internal) and to compare quality of care among different entities (external).68

A. Internal Uses for Osteoporosis Management Performance Measurement

Examples of internal uses for performance measurement in osteoporosis management include:

- Measurement of direct and indirect changes in osteoporosis management processes and patient outcomes in response to QI interventions.
- Assessment of compliance with selected guidelines and evidence-based practices in order to eliminate non-evidence–based approaches to osteoporosis management grounded in habit, opinion, and bias.
- Identification of knowledge, attitudes, and competencies of clinicians.
- Identification of educational needs, individual preferences, beliefs, and expectations about osteoporosis management among patients and their family caregivers.
- Improvement prioritization when multiple opportunities exist.
- Compliance with performance data demands from external sources such as payers and government regulatory bodies.
- Provision of objective data in order to gain support from organizational leadership and buy-in from clinicians for improvement activities.

B. External Uses for Osteoporosis Management Performance Measurement

Examples of external uses for measuring performance include:

- Comparison of performance on osteoporosis management processes and outcomes with those of other organizations.
- Establishment of national, regional, or other benchmarks.
- Validation and refinement of criteria such as guidelines, standards, and care recommendations.
- Evaluation of the effect of these criteria on areas such as patient outcomes, costs, and provider behavior.
- Collection of research data to validate treatment efficacy, evaluate assessment instruments, or establish evidence-based practice.

C. Addressing Concerns Related to Measuring Performance

Although most health care professionals would agree that performance measurement is valuable and necessary for effective QI, it is often met with resistance and apprehension. Lack of familiarity with data analysis methods and tools (e.g., statistical process control [SPC]) can lead to concerns about the ability to understand and

“Quality is never an accident; it is always the result of intelligent effort.”

— JOHN RUSKIN, ENGLISH CRITIC, ESSAYIST, & REFORMER (1819 – 1900)
communicate findings. Prior negative experiences can give rise to perceptions that performance measurement is not valuable or valid. These experiences include:

- Judgments based on insufficient sample size
- Disclosure of misleading data
- Use of measures not based on evidence of relationship to positive patient outcomes

At the organizational level, performance measurement may be perceived as requiring too much dedicated staff time and resources relative to the expected benefit.

Overcoming these challenges requires early communication and ongoing education throughout the organization to ensure everyone understands the purpose of data collection, the measurement methods used, and the ultimate project goals. In general it is best to prepare special communication for management, department heads, and other influential groups to address specific concerns and solicit buy-in.

It is important to choose measurement objectives carefully and consider the impact on related processes of care. It has been observed that measurement may have the unintended result of allocating resources, effort, and attention to targeted areas, possibly to the detriment of other functions. Therefore, careful planning and attention to institutional priorities is important to ensure resources are wisely distributed.

Adopting a systems-level approach to performance measurement and improvement can help overcome the concern that data will be used to single out individuals for criticism. Those charged with implementing such activities must assess data quality and reliability, and use sound analysis and interpretation techniques to ensure data are translated into information that is fully substantiated and can be readily understood. More information about this issue is provided in Section VI: Assessing and Analyzing Your Processes and Results, page 94.

Whether launching new osteoporosis management improvement activities or maintaining established improvements, organizations can enhance effectiveness by:

- Viewing measurement as part of an ongoing process rather than as an end point.
- Exercising care in choosing what to measure.
- Keeping in mind that measurement is most valuable when it is conducted with rigorous attention to quality, analyzed with accuracy, and applied in a timely manner

As Donald Berwick, MD, a widely recognized leader in the QI field has said, “measurement without change is waste, while change without measurement is foolhardy.” Keeping this in mind, organizations can avoid the pitfall of “measurement for measurement’s sake” as well as the negative effects on morale and costs that can result when data are collected but not used. By recognizing and attending to common concerns surrounding performance measurement and use of data, organizations can overcome resistance.

Section II. Using Criteria for Effective Measurement

A. Overview of Criteria

When evaluating osteoporosis management activities, it is important to refer to credible, evidence-based sources for identifying measurement objectives and establishing performance expectations. Examples of possible sources include clinical practice guidelines, standards, consensus statements, and position papers. The first section of this monograph contains several evidence-based measures that can be considered for use in a program of measurement designed to improve osteoporosis management. For purposes of this monograph, all of these items will be referred to as criteria, which are defined as a means for judging or a standard, rule, or principle against which something may be measured.
Guidelines

Guidelines are systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances. Guidelines are often a mechanism by which treatment recommendations are communicated. Osteoporosis management–related guidelines have been developed for different patient populations (female, adult, fragility fracture patients), types of osteoporosis (primary or secondary), conditions, and procedures or treatments associated with low bone mass (e.g., transplants, obesity surgery, glucocorticoid administration, etc.). One source of information on current guidelines related to osteoporosis management is the National Guideline Clearinghouse Web site (www.guideline.gov). A few examples of sources for osteoporosis management guidelines are included in Table 8, below.

TABLE 8. Sample Osteoporosis Guidelines

American Association of Clinical Endocrinologists (AACE): Risk factor assessment

- Evaluation
- Osteoporosis prevention
- Osteoporosis management


American College of Obstetricians and Gynecologists (ACOG)

- Level A, B, and C recommendations for education, screening, and treatment


RAND Health

- Nine indicators; two on prevention (counseling), HRT counseling, identifying secondary osteoporosis, exercise for new osteoporotic fracture patients, calcium and Vitamin D supplementation, corticosteroid use, treatment, testosterone therapy for males


Australian Family Physicians

- Evidence-rated guidelines for assessment and treatment of males


Canadian Medical Association

- Comprehensive guidelines


Institute for Clinical Systems Improvement (ICSI)

- Comprehensive guidelines graded by strength of evidence


Long Term Care Practice

- Recommendations for long term care assessment and management, unrated.


Standard

A standard is 1) a criterion established by authority or general consent as a rule for the measure of quality, value, or extent; or 2) for purposes of accreditation, a statement that defines the performance expectations, structures, or processes that
must be substantially in place in an organization to enhance the quality of care.72
(Note: this definition is distinct from the use of “standard” in a “standard of care,”
which may be used in a legal context or a “standard of practice” established by an
organization). Standards typically are used by accrediting bodies such as The Joint
Commission and Commission on Accreditation of Rehabilitation Facilities (CARF) to
evaluate health care organizations and programs.

Consensus statements and position papers

Consensus statements and position papers are expressions of opinion or posi-
tions on health care issues. They are generally prepared by professional societies,
academies, and organizations and generated through a structured process involving
expert consensus, available scientific evidence, and prevailing opinion. Table 9,
below, provides a sample of sources for consensus statements and position papers
that may provide additional resources for examining osteoporosis management
practice in an organization, developing improvement interventions, and creating
an organization-wide program. One consensus statement of special relevance for
osteoporosis management improvement is that published by the NOF.

TABLE 9. Sample Osteoporosis Position Papers and Consensus Statements

<table>
<thead>
<tr>
<th>Organization</th>
<th>Topic</th>
</tr>
</thead>
<tbody>
<tr>
<td>American College of Rheumatologya</td>
<td>Preventing and treating glucocorticoid induced osteoporosis</td>
</tr>
<tr>
<td>Agency for Healthcare Research and Quality (AHRQ)bc</td>
<td>Risk factors, testing, monitoring, biochemical markers, evaluation for secondary causes, costs of treatment approaches</td>
</tr>
<tr>
<td>International Society for Clinical Densitometry (ISCD)d</td>
<td>Indications for testing, reference databases, Central DXA, terminology, peripheral densitometry age/gender, technical reporting requirements</td>
</tr>
<tr>
<td>Michigan Quality Improvement Consortiume</td>
<td>Evaluation, management, and treatment of osteoporosis</td>
</tr>
<tr>
<td>National Institutes of Health Consensus Development Conference Statementf</td>
<td>Comprehensive guidelines</td>
</tr>
<tr>
<td>The North American Menopause Societyh</td>
<td>The role of calcium in peri- and postmenopausal women</td>
</tr>
<tr>
<td>U. S. Preventive Services Task Force (USPSTI)j</td>
<td>Osteoporosis screen in postmenopausal women</td>
</tr>
</tbody>
</table>

*a Prevention and treatment of glucocorticoid-induced osteoporosis, 2001 update. Arthritis &
b Agency for Healthcare Quality and Research. Osteoporosis in postmenopausal women: diagnosis and
2007.
c Nelson HD, Helfand M, Woolf SH, Allan JD. Screening for postmenopausal osteoporosis: A review of the
f Consensus Development Conference Statement. Osteoporosis Prevention, Diagnosis, and Therapy.
B. Criteria Similarities and Differences

Often, these terms (standards, guidelines, and consensus statements) are used interchangeably throughout the literature and across the health care field by entities ranging from government agencies to accrediting organizations to professional societies to legal experts. Although similarities exist among them, there also are some distinct differences that should be kept in mind to prevent confusion over terminology (see box, below).

Although criteria can be highly beneficial for assessing and improving organizational performance and quality of care, health care organizations must ensure that the sources are credible, evidence-based where applicable, scientifically sound, and accepted by clinicians. As options for managing osteoporosis continue to evolve, it is important to consider the extent to which information in the criteria reflect the current state of knowledge. Some criteria are subject to established cycles of review and revision, while others are not. For example, a study designed to assess the validity of 17 guidelines developed by the AHRQ and to use this information to estimate how quickly guidelines become obsolete, led to the recommendation that, as a general rule, guidelines should be reassessed for validity every three years.73

C. Mandated Criteria

Another important set of criteria consists of those mandated by federal, state, and local statute or regulation. All health care professionals and organizations need to be aware of the statutes and regulations applicable to their practice. A detailed discussion is beyond the scope of this monograph, due in part to the complexity and changing nature of such criteria, and it should be noted that to date there are no statutes or regulations applicable to osteoporosis care.

GUIDELINES, STANDARDS, CONSENSUS STATEMENTS CRITERIA

Similarities Among Guidelines, Standards, and Consensus Statements

- They are useful for establishing expected or desired levels of performance that are credible, evidence-based, and recognized by professionals.
- Scientific evidence and/or expert consensus are used in development.
- They can be multidisciplinary in scope and focus.
- Usually compliance is considered voluntary rather than mandated by law.
- They are useful for improving consistency and reducing variation in care processes and for evaluating links between processes of care and outcome quality management.
- They can serve to educate clinicians, organizations, and others in the health care community regarding advances in the field and subsequent care recommendations.

Differences Among Guidelines, Standards, and Consensus Statements

- The intended audience can vary widely. For example, guidelines are often written for clinicians who deliver care, while standards often are written for a broader audience such as a department or organization.
- Criteria can have different intended purposes. For example, standards of all types are frequently seen as authoritative statements, expectations, or requirements and are used at the level of assessment for organizations or programs. Guidelines, on the other hand, generally are viewed as strategies for clinical decision-making, and hence are more flexible. They also are used to develop protocols allowing for clinically justifiable deviations in treating individual patients or for alleviating specific conditions or symptoms.

The degree of clinical certainty can vary across and even within each criterion category based on the developmental approach used and the availability of documented scientific evidence.
Section III. Understanding Organizational Improvement in Osteoporosis Management

A. Viewing the Organization as a System

Recent trends in health care performance assessment indicate organizations are moving toward systems techniques and approaches that originated in industrial improvement models. A system is a group of interacting, interrelated, or interdependent elements or processes that form a collective entity and share a common goal.74 Taking a systems approach means emphasizing the organization as a whole, focusing on the interconnectivity of processes and underlying structures, recognizing relationships and interactions across the organization, and identifying root causes of problems. Figure 1, below, illustrates how an organization’s culture and leadership affect patients, staff, strategies, and processes.

Similarly, improving osteoporosis management performance requires “systems thinking,” much like that used for identifying opportunities to improve the medication use process.75, 76 The use of a systems approach when designing or redesigning processes requires one to consider ways to overcome potential process or task design failures in such areas as equipment, organizational and environmental factors, psychological precursors, as well as team building and training.77

Strategies for improving osteoporosis management can be viewed in relation to a system composed of:

- Inputs—including patients, clinicians, technology, equipment, pharmacologic and nonpharmacologic therapies
- Throughputs—care processes
- Outputs—including patient satisfaction, outcomes (e.g., morbidity, mortality, changes in clinician behavior) and health care utilization (e.g., emergency department visits for falls, fractures, hospitalization)

Improvement efforts will produce the greatest effect when inputs and throughputs are simultaneously addressed by altering how these elements interact to change outputs.78 As Donald Berwick, MD, has said, “Every system is perfectly designed to achieve exactly the results it achieves.”78 Poorly designed systems often lead to inefficiency and inadequate quality of care. Understanding and simplifying the steps of a process can yield substantial improvements in performance.

“...You must be the change you wish to see in the world.”
— mahatma gandhi

Figure 1. Dynamics of Systems Thinking in Relation to Health Care Organization

![Diagram of systems thinking in health care organization](image-url)
B. Understanding Osteoporosis Management

The rapidly expanding body of evidence-based findings related to osteoporosis management makes it imperative to conduct a review of the latest information available before implementing QI activities. Resources include criteria (guidelines, consensus statements, and standards), journal articles, texts, Web sites, and other publications. Sources useful in identifying reference materials include:

- National Osteoporosis Foundation (www.nof.org)
- International Osteoporosis Foundation (www.iofbonehealth.org)
- Foundation for Osteoporosis Research and Education (www.fore.org)
- The National Guideline Clearinghouse at (www.guideline.gov)

In addition, conferences, professional society meetings, research symposia, and educational seminars are often great sources of new or “cutting edge” information. They also provide the opportunity for staff to gain new skills, network with other organizations, and meet recognized experts in the field.

Participating in research as a test site can be an excellent opportunity for organizations. Benefits may include access to newly developed technology, data collection strategies, education, and support services as well as aggregate comparative information. To learn about research opportunities, check with academic institutions, professional societies, and government agencies (e.g., the Agency for Healthcare Research and Quality). It is important that health care institutions support research through funding, and active participation and dissemination of research findings at professional and scientific meetings. These activities are critical to creating and maintaining exemplary practice in clinical services across all types of settings.

C. Integrating Osteoporosis Management

The process of integrating good osteoporosis management practices into an entity’s daily operations requires a comprehensive approach that includes—and goes beyond—performance improvement (PI). Barriers must be overcome to achieve fundamental system changes.

Interdisciplinary approaches may take several forms – Six Sigma, (a disciplined, data-driven approach and methodology for eliminating defects referring to six SDs between the mean and the nearest specification limit), Plan-Do-Study-Act (PDSA), or another of the variety of approaches that have worked for some organizations. The important thing to remember is to choose an approach that works for your organization. Carefully evaluate the successful efforts of the past. What were the essential factors of those approaches that can be utilized again in effecting the necessary changes in your organization? Those successful strategies can provide a foundation for system change and effective PI activities that lead to enhanced care for your osteoporosis patients.

Whichever approach is chosen to integrating osteoporosis management into your organization, there are activities that are common to all modern QI methods. These include forming a multidisciplinary committee of key stakeholders, analyzing current osteoporosis management practice performance, and improvement through continuously evaluating performance. Although these steps are common to a QI initiative, they may differ in scope. For example, the multidisciplinary committee charged with integrating quality osteoporosis management throughout the organization will often be addressing mission and policy statements, standards of care, accountability, and overall practice issues. By contrast, a QI work group generally has responsibility for a focused improvement activity (see Section IV. A. Establishing the Project Team, page 75). Depending on the size of the organization and available resources, the committee may fulfill both roles.

D. Understanding Current Osteoporosis Management Practices at Your Organization

One of the first priorities is to complete a comprehensive evaluation of the organization’s structures, processes, and people, referencing key criteria for quality osteo-
porosis management practices. This organizational assessment may involve multiple
data collection activities, including review of organizational resources, documents,
and medical records; completion of a self-assessment tool; and assessment of staff
knowledge and attitudes. These measurement approaches, including references for
organizational self-assessment instruments, are further described in Section V. Mea-
suring What You Need to Know, page 79.

Understanding patient factors is essential to completing the picture of current
management practices. No osteoporosis initiative can succeed if patient needs are
not carefully evaluated and addressed. Patient-related considerations that may fig-
ure significantly in designing an osteoporosis management improvement activity
include:

- Specific special-risk groups, such as the elderly, those on certain medications
  (such as glucocorticoids) those with impaired intestinal function, or those with
  a history of solid organ transplant
- Special osteoporosis considerations for those with fragility fracture
- Information obtained about current osteoporosis screening compliance

Obtaining objective data related to these patient and institutional factors will
result in a better evaluation of organizational performance. A thorough understand-
ing of your organization’s current practices will provide a solid foundation for iden-
tifying ways to improve and is an important step toward making recommendations,
gaining needed support, and designing successful improvement interventions.

E. Understanding Quality Improvement Principles

The past decade has been marked by an evolution in health care toward the use
of modern QI methodologies. Although several different frameworks exist, virtually
all include defined steps that function as an operational model for implementing
improvement processes. Figure 2, below, presents the widely used PDSA framework
developed by Langley et al.
**The Cycle for Improving Performance**

This monograph has adopted The Joint Commission’s Framework for Improving Performance, which includes a cycle similar to the PDSA cycle. The Joint Commission Cycle for Improving Performance describes critical activities common to many improvement approaches and provides for systematic, scientifically oriented action (Figure 3, below). The cycle is one component of the framework that also recognizes factors in the external and internal environment that influence organizational performance.

As shown in Figure 3, the cycle is a continuous process with four major activities: design, measure, assess, and improve. All four activities are important and must be addressed to achieve a balanced, effective approach. In the design phase, a function or process is created. In the measure phase, data are gathered about the process to create an internal database for evaluating performance. In the assess phase, data are analyzed to identify areas for improvement or to assess changes. In the improve phase, changes required to improve upon the original function or process are implemented. This highly flexible cycle allows health care organizations to begin at any phase, and apply it to a single activity or an organization-wide function.

**FIGURE 3. Cycle for Improving Performance**

![Diagram of the Cycle for Improving Performance](source: Joint Commission Resources. Using Performance Improvement Tools in Health Care Settings, 3rd ed. Oakbrook Terrace, IL: Joint Commission Resources; 2006. Used with permission.)

**Repeating the Cycle at Different Phases of the Project**

Whether one selects the PDSA cycle, the Framework for Improving Performance, or a different approach, most improvement initiatives will require repeating the cycle for different phases of the project. For example, if the quality management staff has identified infrequent dietary counseling after a fragility fracture as a problem, they may take steps to organize a team involving physicians, nurse managers, and nutritional counselors to determine an overall goal for improving educational practices (design/plan); use self-assessment tools and medical record audits to measure the extent of the problem across the organization (measure/do); collect and analyze data on dietary counseling through medical record audits on representative patient care units or populations (assess/study); and prioritize potential improvement options and implement interventions (improve/act).

After agreement among staff members that a multifaceted educational intervention is needed, the cycle would repeat itself. The education would be planned across shifts (design/plan), the education would be implemented as a pilot test on a single unit or division by having staff complete a pretest examination before the education (measure/do), the education would be conducted (improve/act), and a post-test examination would be completed and the change in scores would be analyzed (assess/study). At that point, the education would be modified as needed and incorporated into orientation and other required education activities.

Table 10 provides examples of some different activities associated with the cycle for each phase of the improvement initiative.
### TABLE 10. Examples of Tasks Associated with Each Stage of the Improvement Cycle

<table>
<thead>
<tr>
<th>Phase of Quality Improvement Initiative</th>
<th>Design/Plan</th>
<th>Measure/Do</th>
<th>Assess/Study</th>
<th>Improve/Act</th>
</tr>
</thead>
</table>
| Understanding the problem              | ■ Organize team  
■ Set overall project goals  
■ Integrate with organizational priorities | ■ Collect baseline data | ■ Compare to established norms  
■ Identify opportunities for improvement | ■ Identify potential actions  
■ Prioritize actions |
| Implementing the improvement/intervention | ■ Set target goals, desired levels of performance  
■ Plan intervention schedule  
■ Obtain resources, approvals | ■ Pilot-test intervention  
■ Collect pilot data  
■ Collect data to evaluate effectiveness of intervention | ■ Assess effectiveness of pilot (redesign if necessary)  
■ Analyze data on intervention effectiveness  
■ Compare results to goals | ■ Implement full intervention |
| Continuous monitoring                   | ■ Determine who, when monitoring will be done how  
■ Re-measure at regular intervals | ■ Reanalyze periodically  
■ Disseminate findings | ■ Modify intervention if needed  
■ Identify new opportunities for improvement |

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**Integrating with Internal Quality Improvement Activities**

Ideally, osteoporosis initiatives should be integrated into existing improvement functions. Taking advantage of established institutional improvement structures will help ensure support of key leadership and involvement of staff with QI expertise and dedicated resources. Look for ways to emphasize osteoporosis management improvement within the context of overall organizational improvement goals. For example, if there is already a team involved in improvement of care for post-operative hip fracture patients, introduction of the osteoporosis initiatives for fragility fracture patients into that work group could be highly advantageous.

It is useful to examine previous successful PI initiatives at your organization to identify the factors that lead to success. Studying successful osteoporosis improvement initiatives completed by other organizations also can be valuable. This can be done by:

■ Networking through professional societies
■ Using Web-based information from other organizations
■ Attending educational conferences
■ Participating in learning networks and organizational PI workshops such as those offered by the Institute for Healthcare Improvement (www.ihi.org) or Joint Commission Resources, Inc. (www.jcrinc.com)
Section IV: Designing your Osteoporosis Management Improvement Initiative

A. Establishing the Project Team

The composition of the project team is extremely important to the success of the improvement project. As with any health care issue, it is important to include key stakeholders, including people with the necessary knowledge and skill in care processes, “change champions” (motivated individuals who reinforce effective osteoporosis management techniques and influence peers), and those individuals with the authority to support change (administrators). Improving osteoporosis management may require the participation of multiple groups within an organization or multiple persons in an entity, and the team should reflect the interdisciplinary nature of the process. As major decision makers, physicians should be engaged early in the planning stages, or efforts to change care are likely to fail.80 Some suggestions for engaging physicians in QI activities are presented in the box.81

The way to get started is to quit talking and begin doing.

— WALT DISNEY
GETTING PHYSICIANS INVOLVED IN THE QUALITY IMPROVEMENT PROCESS

Eight questions to ask:
- Do physicians in your organization feel excluded from the team at the outset?
- Are incentives poorly defined and identified?
- Is the team too rigid in laying out its tasks?
- Are goals and objectives vague or unrealistic?
- Are there too few data, or is there misuse of data?
- Is there a solid connection between the problem and its relevance to patient care?
- Does the approach emphasize scientific methods?
- Does the team have the needed expertise in continuous QI techniques, skill measurement, and data analysis (i.e., a data analyst or statistician)?

Eight solutions to consider:
- Choose an important project with clear goals.
- Include physicians on the ground floor. Ask what QI issues they would like to see measured and monitored.
- Focus on data that are readily available, timely, and valid.
- Adjust outcomes data appropriately to avoid misuse.
- Recognize physician bias. Usually, physicians care more about clinical outcomes and less about QI processes. Clearly identify benefits of QI to physicians and their patients.
- Use physician time wisely: avoid meetings during office hours, and use fax, phone, teleconferencing, and e-mail as alternatives to face-to-face meetings.
- Avoid engaging physicians in activities that require long training sessions and excessive use of QI terminology.
- Strive to involve a few physicians who are opinion leaders.


WHAT ARE MEDICAL GROUPS DOING ABOUT QUALITY?

Simultaneous surveys were sent to medical and administrative leaders of 18 medical groups, 84 constituent clinics, and their primary care physicians in the Minneapolis-St. Paul metropolitan area to survey QI priorities and activities.

Of the 18 groups, 17 had a physician leader for QI and 11 had the same at their constituent clinics. Nearly 100% of clinic leaders reported that group leaders see QI as important and expect care improvement, while 69%-84% of the physicians reported that clinic leaders were committed to QI for diabetes and heart disease. Only seven groups reported adequate QI resources and only three groups reported that incentives are aligned with quality.

These medical groups and their constituent clinics and physicians appeared ready to work on QI, but believed that limited resources and financial incentives that were not aligned with quality constrain their ability to help America cross the quality chasm.


Because the osteoporosis management process could potentially involve many individuals, it may be practical to develop a core group and enlist additional members who participate as necessary on specific issues. Be sure to keep all members informed, especially if they do not attend all meetings, through communications proven to be most effective in your organization, such as minutes, e-mail, phone, or newsletters.

Once the team is identified, define and assign roles and responsibilities. Another approach used by some organizations, utilizes a “contract,” or written statement of responsibilities and commitment for team members.
Several additional factors important to successful implementation of QI teams are shown in the box, below.82

### COMMON CHARACTERISTICS OF SUCCESSFUL QUALITY IMPROVEMENT TEAMS

- Clear goals and a written charter
- Clarity of each member’s role
- A standard process for team meetings and the team’s work
- Trained and oriented team members
- External support and recognition
- Effective leadership and facilitation
- Collaborative problem solving and decision making
- Presence of leadership with the resources to implement proposed solutions
- Time for team meetings and assigned team work


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**B. Selecting Objectives and Target Goal**

Once the team is in place, the next step is to define objectives for the organization’s measurement efforts. As previously noted, criteria (such as those described in Section II. Using Criteria for Effective Measurement, page 66) provide valuable evidence-based principles and processes for evaluating osteoporosis management. Improvement opportunities may be identified by comparing your organization’s current practice (using objective assessment data) with criteria.

If multiple opportunities are identified, objectives need to be prioritized, with one or two eventually selected. Objectives should be manageable and measurable, and should reflect expectations that are meaningful to patients as well as to health care professionals. The following statements are examples of objectives:

- Patients age 50 or older with fractures will undergo BMD testing within three months of the fracture date.
- Female patients age 65 and older will have at least one BMD test.
- Osteoporosis patients will have home safety education to decrease the risk of falls.

Some organizations may further define the objective by adding a target performance goal. For example, the first objective could have an assigned target goal of 90%. The target goal describes a desired level of performance and serves as a “ruler” for measuring improvement. At the same time, setting incremental goals may provide positive incentives as success is achieved in a defined way.

**C. Establishing the Scope of Measurement**

Once the team determines what to measure (setting the objectives), it needs to decide the scope of measurement. Measurement options can be defined in a number of ways:

- Discipline-specific measurement focuses on a particular discipline (e.g., nursing, medicine, dietary) and probably is most applicable when the intervention is exclusive to the measured group and discipline-specific knowledge and skills can be assessed.
- Service or unit-specific measurement may be useful when the improvement activity is limited to a specific area such as an emergency department or home health unit.
Population-specific measurement based on diagnoses or symptoms targets a defined patient group—possibly across more than one unit, organization, or health plan—such as patients on glucocorticoids.

Organization-wide measurement deals with all patients and service areas and is useful when implementing process changes, such as consistent use of a specific home safety checklist, depending on the data collection method.

Health system-wide measurement looks at organizations within the same administrative management system and is used when assessing activities across multiple sites. For example, a multi-state chain of long term care facilities records BMD testing status for all female patients age 65 and older.

Finally, the scope of measurement should be aligned with stated measurement objectives and target goals. To illustrate, it would be insufficient to measure a single unit for an organization-wide objective.

A CLAIMS-BASED ALERT SYSTEM

ActiveHealth Management, with offices in several U.S. cities, is a clinically-based, technology-driven health management services company. In 1998, a claims-based clinical alert system was developed to communicate potential clinical opportunities to health care providers and covered members. The osteoporosis alerts were developed from guidelines for osteoporosis screening and treatment in postmenopausal women, hypogonadal males, and men and women with fractures or chronic steroid use. The patient-specific alerts were communicated only if there were no prior claims evidence of osteoporosis treatment or BMD evaluation. Following communication of the alert, compliance with the guideline recommendations was assessed by reviewing claims for evidence of either bone density evaluation or osteoporosis treatment in the six months following the alert.

From 2004 to 2006, 204,407 alerts were issued for commercial, Medicare, and Medicaid populations. Compliance rates were as follows:

<table>
<thead>
<tr>
<th>Clinical Risk Factor</th>
<th>Total Number of Alerts Delivered</th>
<th>Compliance Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fragility fracture, women</td>
<td>40,146</td>
<td>18.3%</td>
</tr>
<tr>
<td>Fragility fracture, men</td>
<td>11,879</td>
<td>6.9%</td>
</tr>
<tr>
<td>Chronic steroid use, women</td>
<td>6,967</td>
<td>23.4%</td>
</tr>
<tr>
<td>Chronic steroid use, men</td>
<td>6,983</td>
<td>13.3%</td>
</tr>
<tr>
<td>Postmenopausal women</td>
<td>123,841</td>
<td>17.1%</td>
</tr>
<tr>
<td>Hypogonadal men</td>
<td>14,591</td>
<td>7.1%</td>
</tr>
</tbody>
</table>

ActiveHealth concluded that a technology-driven, claims-based clinical alert system can be used to identify gaps in care and can lead to improved guideline implementation.


D. Identifying Resources and Project Timeline

The final steps of the planning process include determining necessary resources and a timeline. Resources will be needed to support the QI team’s work as well as to implement improvement interventions. Improvement interventions may involve patient-care related equipment (e.g., stadiometers for height assessment), written materials (e.g., educational booklets, instructions) and media (e.g., teaching videos). Project-related resources may include equipment (e.g., computers, printers), supplies (e.g., paper, flip charts, poster-boards) and staff time (e.g., for data collection, analysis, meetings, attendance at educational programs). Whenever possible, adapt and adopt from existing resources to save precious staff time and benefit from previous research.
Finally, the team must develop a timeline based on realistic estimates for each step of the project; underestimating the amount of time required is a common pitfall. Important project steps include the baseline performance assessment, pilot testing, redesign (if indicated), retesting, full-scale implementation, and time to establish intervention-related changes. The timeline can be as short as a few weeks for simpler improvement efforts or as long as several years, which may be required to complete comprehensive QI projects.

Section V: Measuring What You Need to Know

In the design/planning phase, specific objectives and the scope of measurement for the improvement activity are identified. Careful planning to select project objectives that are measurable will help your organization prepare for the next step: data collection. Data collection is used throughout the improvement project, beginning with the assessment of current performance and continuing during and after interventions to document change. Deciding how to collect the data (i.e., the measurement approach) is an important decision. Several considerations when selecting an approach are discussed in this section, and several measurement approaches are presented.

A. Consider Your Measurement Approach

Measurement involves the collection of specified values or facts. The data selected for collection should support analysis of the goals and objectives identified for the project. The method used in data collection, together with the identified data source(s), constitutes the measurement approach. In some instances the approach includes well-defined data elements and collection processes such as those required for the NCQA HEDIS data measures or for participation in a performance measurement system. In other approaches, the organization-specific data elements, sources, and collection process will have to be identified. However, it is important to maintain perspective on the data collection effort. Occasionally, over-analyzing the clinical processes in osteoporosis care can lead to exhaustive data collection efforts, and details are captured that have little relevance to change and achievement of improvement in care.

Many options exist for measuring performance. In Section V. C (Selecting a Measurement Approach, page 83), the following measurement approaches are described:

- Conduct organizational self-assessment
- Review medical records
- Test knowledge and attitudes
- Directly observe the care
- Conduct a point prevalence study
- Assess patient status and outcome over time
- Collect indicator data
- Utilize an externally developed performance measurement system.

Regardless of the method or measurement approach selected, there are some common data collection issues to consider. Obtaining quality data that can support performance assessment is critical to a successful improvement initiative. The following provides an overview of the issues of data quality, data quantity, and use of data collection instruments.
Improving and Measuring Osteoporosis Management

Data Quality
Ensuring data quality is an essential component of the measurement initiative. High-quality data are needed to establish the validity of the measurement and improvement initiative (e.g., the extent to which the concept being assessed is accurately measured and that the improvement is a true improvement). There are several issues to consider relative to data quality. Some issues apply at the data element level, while others apply after data elements have been aggregated (e.g., indicator rates). Data quality issues can be described by using the concepts of accuracy, completeness, and consistency.

Accuracy
The accuracy of information at the data element level is a function of the definitions (e.g., clarity and thoroughness), categorizations (e.g., whether categories are appropriate, comprehensive, and mutually exclusive), and the overall clarity and readability of the instructions and documentation (e.g., inclusion and exclusion criteria). Often, it is necessary to describe a preferred source of data, because even simple items like patient age can be recorded differently and in more than one place (e.g., on the chart versus in the admission database or electronic health record). When aggregating multiple data elements to arrive at calculated values (e.g., rates), the number and complexity of steps can affect the accuracy of the information.

Completeness
Completeness refers to the extent of missing data. The more data elements needed, the greater the opportunity for missing data.

Consistency
Consistency is often referred to as reliability. Reliability is the extent to which the measure or data collection tool, when repeatedly applied to the same population, yields the same results a high proportion of the time. To enhance consistency, one may want to consider these questions: Are different departments using different educational tools? If all units are using the same tool, then are all staff being instructed consistently in how to use the tool? Will data collection be completed by a few individuals, or many staff members? How will consistency between data collectors (inter-rater reliability) be ensured?

No data source or data collection process is perfect; there are always trade-offs to consider. For example, data from automated sources may be more reliable than data that are manually abstracted, but the information in automated sources (e.g., administrative) may be less clinically robust. Using scannable forms can decrease errors associated with data entry, but may limit the types of responses that can be entered. In general, as more people become engaged in data collection, the reliability of the process decreases. However, limiting responsibility for data collection to one or two people risks the possibility that staff turnover, illness, or reassignments can substantially derail your project. This potential problem can be mitigated somewhat by cross-training people to perform different functions.

Data quality can be greatly enhanced by formal training and testing of data collection procedures. These steps may initially require extra time and resources, but will result in enhanced credibility of results and buy-in from stakeholders in the long run.

Early in the process, it is important to determine how you will monitor the quality of your data. Remember that monitoring data quality needs to be done at regular intervals, determined by the length of project. Examples of different approaches are provided in the box, below.
Data Quantity

A second consideration is the quantity (amount) of data you will need. Quantity is affected by both the total amount of data needed and the frequency with which data are collected. The amount of data needed depends on the type of analysis you plan to do and the level of confidence you want to have in your results. If you plan to use sophisticated statistical analyses and/or intend to generalize your findings from a sample to the population, you may want to use a power analysis formula to calculate the necessary sample size. See Scheaffer et al.84 and Fowler85 for more information on sample size issues. Further, an online random sample calculator is available at www.custominsight.com. Statisticians frequently recommend a minimum of 30 cases in each group for analysis. It is always wise to consult with the experts on sample size issues.

If you cannot collect data on all patients in the population of interest, you can use sampling techniques to reduce the data collection effort. One example of a simple method for selecting a systematic random sample is provided in Managing Performance Measurement Data in Health Care.82 The steps are as follows: 1) obtain a list of patients in the order in which they were treated, 2) count the number of patients on the list, and 3) divide by the number needed for the sample size. The resulting number will be the interval between one patient on the list and the next patient on the list who is to be selected for the sample. In other words, if the list has 300 patients and the needed sample size is 50 cases, every sixth (300/50 = 6) patient record would be selected for data collection. To make sure each patient has an equal chance of being selected, it is helpful to pick the starting point randomly (using a random numbers table or a die). Some commercial software programs, such as Microsoft Excel, include a random sampling procedure. Selected approaches to sampling are shown in the following box.

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**EXAMPLES OF APPROACHES TO MEASURING DATA QUALITY**

- **Data collection software.** The use of data collection software allows for built-in edits to promote data integrity. This is a benefit of using an automated approach to collect data because some errors can be found and corrected at the point of data entry. Also, missing data can be minimized by software prompts alerting the user of needed responses.

- **Periodic re-abstraction by a person other than the usual data collector for a sample group of patient records.** This approach is commonly used for manually abstracted data on a monthly or quarterly basis. A certain number or percentage of patient records are pulled at random, and someone re-abstracts the same data by using the same data collection tool as the original data collector to determine an error rate. This method is referred to as “inter-rater” or “inter-observer reliability.” Frequently occurring errors are investigated to determine possible causes, and actions are taken to prevent the errors from recurring.

- **Duplicate data entry.** Companies that specialize in survey research often require all or a subset of data to be entered twice (by two people or one) to assess and ensure accuracy in data entry.

- **Run aggregate frequencies and means on individual data elements and rates.** The first step in data analysis is most useful to identify data quality problems. Typically, one uses database software (such as Microsoft Excel® or Microsoft Access™) to identify cases with missing values as well as outlier values (e.g., ages older than 200 years, heights greater than seven feet). One then needs to follow up with original data sources to confirm or correct inaccurate information.

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B. Collecting Data with Established Assessment Instruments

Organizations should use structured data collection tools, which can be paper forms and/or electronic data entry screens. They may choose to develop these forms or programs themselves, or adopt or adapt one developed by others. The result is a wide array of materials ranging from a simple chart abstraction form to a sophisticated clinical assessment product. The following definitions are provided to differentiate between various types of tools.

Data collection tool: A user-friendly composite of indicators, trigger questions, or statements aimed at eliciting performance data about specific issues of concern.86

Quality improvement tools (PI tools): A collection of tested activities and nonstatistical and statistical methods designed to facilitate the process of improvement. An example of one of these tools is the cause-and-effect diagram, also called a fishbone or Ishikawa diagram. QI tools are further described in Section VI (Assessing and Analyzing Your Processes and Results), page 94.

Patient assessment instruments: Tested data collection tools designed to obtain structured information about patient health status and levels of functioning. An example of clinical assessment instruments is the SF-36 Health Survey.87 The widely used SF-36, which can be self-administered by persons older than age 14 years or by using trained interviewers, measures the following eight health concepts:

1. Limitations in physical activities because of health problems
2. Limitations in usual role activities because of physical health problems
3. Bodily pain
4. General health perceptions
5. Vitality (energy and fatigue)
6. Limitations in social activities because of physical or emotional problems
7. Limitations in usual role activities because of emotional problems
8. Mental health (psychological distress and well-being).

Permission to use the SF-36 Health Survey can be obtained from the Medical Outcomes Trust at www.outcomes-trust.org. There are other assessment instruments described at that website, as well. Another resource for general surveys to help develop patient-centered care may be found at www.CAHPStools.gov, where a variety of surveys (adult primary care, health plan care, etc.) may be accessed.

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EXAMPLES OF APPROACHES FOR SELECTING SAMPLES

- **Simple random sampling** is a process in which a predetermined number of cases from a population as a whole are selected for review. It is predicated on the idea that each case in the population has an equal probability of being included in the sample.
- **Systematic random sampling** is a process in which one case is selected randomly, and the next cases are selected according to a fixed interval (for example, every fifth patient who undergoes a certain procedure).
- **Stratified sampling** is a two-step process. First, the population is stratified into groups (e.g., male/female); second, a simple random sample is taken from each group.
- **Cluster sampling** is a process in which the population is divided into groups; then some of the groups are selected to be sampled.
- **Judgment sampling** is a process in which experts in the subject matter select certain cases to be sampled. Unlike the previously mentioned “probability” sampling techniques, this form of sampling is considered a “nonprobability sample.” It is likely that the sample group will not represent the population’s characteristics. However, the experts selecting the cases may be trying to change a particular process.

It is useful to consider several issues when selecting clinical assessment instruments developed by others. One should determine whether and how the instrument has been evaluated for these issues. Do the results indicate the instrument can be applied successfully to your organization's patient population? Are there cultural, literacy, or language issues that need to be addressed? Learning about the development and testing of an instrument will help ensure that it will support collection of data that are meaningful and meet your PI goals.

**Osteoporosis-specific Instruments**

No commercially-available instruments have been developed by researchers to assess specifically for the impact of osteoporosis on the individual's activities of daily living. However, there are several multi-use instruments available which, when administered to a select group of patients, can be useful in assessing the effects of osteoporosis.

**Choosing Osteoporosis Assessment Instruments**

Considerations when selecting instruments for measuring aspects of osteoporosis care include:

- The type of patient to be evaluated—fracture patients, other osteoporosis patients, etc.
- The measurement goals—Are you assessing multidimensional aspects of osteoporosis?
- Characteristics of the patient population—(e.g., language, cognition, age, cultural factors).
- Resources required/ease of use—Consider the comfort of staff members with using the tool, the ability of patients to use the tool, the time needed to administer the tool, and appropriateness and interpretability.
- Reliability—An osteoporosis assessment instrument should be reliable, meaning that it consistently measures perceptions about osteoporosis or osteoporosis care from one time to the next.
- Validity—There are a number of different types of validity (e.g., construct, convergent, predictive, concurrent). The validity of assessment instruments has been defined as the degree to which the instrument measures what it purports to measure.

Each instrument has advantages and disadvantages that should be understood and considered.

**C. Selecting a Measurement Approach**

When considering which measurement approach to use, there are certain questions to keep in mind. These include:

- Does the method match/support the measurement objective? For example, use of a point prevalence study to measure events or processes undergoing rapid change and with great variability may not yield sufficient or meaningful data.
- Which approach provides the most reliable and highest quality data, and the least bias and subjectivity, which will minimize missing data?
- What are the available data sources? One should assess for data availability, but do not let data alone determine your measurement goals. In many organizations—especially large ones—data may be collected but kept within individual departments and therefore cannot be routinely shared with others, or data may be collected in more than one place. For example, data regarding osteoporosis dietary education may be documented in a nutritional logbook as well as in the individual medical record.
- What is the most economical option that fulfills measurement requirements? Consider the data collection burden (e.g., time to collect the data, the staff

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*Do not put your faith in what statistics say until you have carefully considered what they do not say.*

— WILLIAM W. WATT
needed, access to/use of automated information systems) against the benefits derived. For example, could data retrieved from an automated administrative database (e.g., pharmacy ordering) be used to collect measure data, or is medical record review required?

- Will the measurement strategies selected be sensitive enough to capture changes that occur as a result of the intervention, and support assessment of the impact of the intervention?21

The following sections outline common measurement approaches used in health care. However, these approaches are not the only options available. A description of the method, suggested applications, and resource considerations are provided for each method discussed.

**Conduct an Organizational Self-assessment**

**Definition/description of method**

This method is used to determine an organization’s status in relationship to targeted areas of performance. It involves the collection of organizational data using a comprehensive structured instrument that captures key structural and process elements associated with performance across the organization. These include information about the structures that support osteoporosis management, such as written mission and policy statements, staff qualifications/credentials, staffing patterns, forms for documentation, capital resources, information management systems, and organizational management style.

**Applications**

Organizational self-assessment is critical in establishing a baseline of the organization’s or entity’s performance in osteoporosis management and identifying potential opportunities for improvement based on objective data. It also can be used over time to conduct ongoing evaluations of the organization’s performance.

**Resource considerations**

Conducting an organizational assessment will require staff time and use of a developed tool. It is beneficial to involve multiple people in the process to obtain input from several perspectives.

There are organizational self-assessment tools and worksheets designed to help focus QI activities. Examples of such tools in The Joint Commission’s *A Guide to Performance Measurement for Hospitals*® include assessment of stakeholders outcomes, data/information needs, assessing organization commitment to performance measurement and improvement, and determining areas for organization improvement.

**Review Medical Records**

**Definition/description of method**

Medical record review (also known as an audit) is the process of ensuring that medical records properly document patient care. The process can take place either while care is being provided (referred to as open or concurrent review) or after the patient has been discharged from the health care organization or concluded his/her episode of care (referred to as closed or retrospective review).

Medical records are reviewed with a structured review tool for completeness and timeliness of information, and the presence of specific data is authenticated. In relation to osteoporosis management, a record audit can capture critical pieces of information about osteoporosis care, such as:

- The timing and types of education provided (dietary, safety).
- BMD assessment.
- Consideration/prescription of pharmacotherapy.
This review often is completed on a representative sample of records as discussed in Section V. A. (Data Quantity), page 81.

**Applications**

The medical record review can be useful at several stages of the improvement initiative, including determination of current practices at your organization, identification of areas for focused review and improvement opportunities, measurement of baseline performance before implementing an intervention, and measurement of performance change against the baseline.

**Resource considerations**

Medical record review generally involves staff time and requires the use of a defined data collection tool. Hard copy records will require manual review by a staff member. When the medical record is computerized, this can be an automated process.

**Test Knowledge and Attitudes**

**Definition/description of method**

This method uses a standardized instrument to assess knowledge, attitudes, behaviors, or perceptions of a targeted group, such as staff nurses. An instrument is administered before an intervention to determine learning needs and after an intervention to assess change in knowledge, attitudes, or behaviors (pre-testing/post-testing).

**Applications**

This method is very useful as part of initial and ongoing assessment of organizational performance in osteoporosis management. It is important to assess knowledge, attitudes, and perceptions of patients as well as staff.

**Resource considerations**

The primary resource required for this method is time for administration of the assessment or testing instrument and interpretation of results.

**Directly Observe the Care**

**Definition/description of method**

This method involves watching and noting the behavior of and/or interactions between caregivers and patients/customers. Typically, a process of care performed by a clinician is observed by a specially trained third party, who objectively notes each activity using structured methods of observation and documentation.

**Applications**

Observational measurement can be useful for circumstances where the subject is unaware, unable, and/or hesitant to report, or lacks awareness of the events and activities that are wanted. For example, it can be used for observing professionals in the course of performing routine care processes, such as osteoporosis home safety counseling. It is best used when the observer is unobtrusive and events being observed are routine and familiar. It is not considered a good choice for unpredictable events/behaviors and events that are of long duration.

**Resource considerations**

This method will require observers with appropriate training and qualifications. It is time intensive and therefore costly. Also, the subject of the observation may alter his or her behavior due to the presence of the observer. However, this method offers unique advantages over other approaches in that it allows researchers...
to assess the quality of interactions and qualitative factors that cannot be captured in documentation.\textsuperscript{90}

**Conduct a Point Prevalence Study**

**Definition/description of method**
Point prevalence is the measure of a condition in a population at a given point in time.\textsuperscript{92} A point prevalence study involves use of a scientific approach to collect data for calculating a point prevalence rate. Data are collected at designated intervals (e.g., quarterly or annually) on the occurrence of a specific event or outcome of interest for a defined period of time such as one week or one month.

**Applications**
This method has wide applicability and can be helpful in reducing the burden of data collection, especially when the cost of continuous data collection exceeds the benefit. Alternatively, when targeted goals of performance have been achieved, it can be used for ongoing monitoring to ensure that performance is not deteriorating. For example, if a PI team has demonstrated 100% compliance with an improvement initiative to document smoking and alcohol counseling for osteoporosis patients, the team may decide to monitor performance using a sample of charts at regular intervals (e.g., one day per month) rather than reviewing all charts.

**Resource considerations**
Data collection may be automated or require manual review depending on the data source. These considerations, as in all methods, will determine the type of resources necessary. A sound method for determining the interval and time frame for data collection should be used to ensure that measurement objectives are met.

**Assess Patient Status and Outcome Over Time**

**Definition/description of method**
This method involves the repeated measurement of strategic patient factors and characteristics with established assessment instruments in an effort to demonstrate change over time.

**Applications**
This essential but underutilized approach provides critical information about various aspects of patient status and outcomes. Measurement for osteoporosis management can focus on areas of dietary compliance or medication compliance.

*Patient satisfaction* - This information can provide valuable insight into the quality of care as viewed by the recipient or family caregiver and may identify opportunities for improvement. It is important to remember that satisfaction and improved osteoporosis care are not synonymous. Patient satisfaction with osteoporosis management efforts can be high even in the presence of unimproved care. Examples of instruments capturing patient satisfaction are included in Section V. B. (Collecting Data with Established Assessment Instruments, page 82). Other sources include proprietary tools from companies specializing in patient satisfaction measurement, although these are not specific for osteoporosis.

*Functional status* - Functional status refers to the evaluation of the ability of an individual to safely perform activities of daily living such as walking, bathing, and dressing. Sometimes these elements can be incorporated into osteoporosis-related assessment instruments, or there are specific functional assessment instruments.

*Multiple dimensions of functioning* - These instruments obtain an overall assessment of health status. Examples of such tools include the Resident Assessment Instrument used in the MDS, which is administered to patients in long-term care facilities, and the Outcome and Assessment Information Set (OASIS), which is administered to Medicare patients receiving home care.
Knowledge and attitudes related to osteoporosis management - Testing the knowledge and attitudes of patients can provide significant insight into behavior and potential barriers to effective osteoporosis management. For example, it has been reported that some patients who sustain fragility fracture have discontinued taking osteoporosis medication when the fracture is healed, believing that the osteoporosis is “cured” as well.

Resource considerations
Resources often will be determined by the complexity of the instruments used. Analysis of changes in data over time may require statistical support.

Collect Measure Data

Definition/description of method
A performance measure, also known as an indicator, is a quantitative tool that provides an indication of performance in relation to a specified process or outcome. Developing a clinical performance measure can be a complex and difficult task. Measures, like guidelines and instruments, should reflect certain attributes to make them credible and effective. Characteristics or attributes of good measures have been defined by multiple organizations experienced in health care measurement. See Table 11 for some suggested desirable attributes against which performance measures should be reviewed.

In general, a good measure should raise important questions about the processes or outcomes of osteoporosis management such as assessment, documentation, education, and treatment selection, as well as identifying opportunities for improvement. A good measure also should encourage a search for underlying causes or explanations of collected data. Toward that end, measures should focus on osteoporosis management processes or outcomes that are within the organization’s control; the measures should be clearly defined, understandable, and able to be reported in a manner that is accurate, easy to interpret, and useful. A measure is useful when it reflects concerns of patients, providers, regulators, accreditation bodies, or other stakeholders and is able to discern variation and improvement in performance.

One of the attributes of a measure that is extremely important, yet problematic, is that the population being examined (defined denominator and numerator) must be retrievable with reasonable effort. For example, in osteoporosis management it is widely recognized that individuals with a low BMI are considered to be a high risk for osteoporosis, and examining that population for assessment of fracture risk is highly desirable. However, retrieving that population for record review is highly problematic, since BMI is not usually recorded as a separate data element upon which a search for records can be done. Similarly, those with low bone mass who are osteopenic, but not yet osteoporotic, should receive preventive interventions, but again that population typically is difficult to identify because there is no specific code for osteopenia.

Finally, a good measure includes complete specifications for consistent implementation and application. Specifications should encompass detailed definitions and specific codes for each data element to be recorded, and an algorithm to assist in data retrieval is especially helpful.
 TABLE 11. Desirable Attributes of Measures

<table>
<thead>
<tr>
<th>Attribute</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Importance of topic area addressed by the measure</td>
<td></td>
</tr>
<tr>
<td>1A. High priority for maximizing the health of persons or populations</td>
<td><strong>The measure addresses a process or outcome that is strategically important in maximizing the health of persons or populations.</strong> It addresses an important medical condition as defined by high prevalence, incidence, mortality, morbidity, or disability.</td>
</tr>
<tr>
<td>1B. Financially important</td>
<td><strong>The measure addresses a clinical condition or area of health care that requires high expenditures on inpatient or outpatient care.</strong> A condition may be financially important if it has either per-person costs or if it affects a large number of people.</td>
</tr>
<tr>
<td>1C. Demonstrated variation in care and/or potential for improvement</td>
<td><strong>The measure addresses an aspect of health care for which there is a reasonable expectation of wide variation in care and/or potential for improvement.</strong> If the purpose of the measurement is internal QI and professional accountability, then wide variation in care across physicians or hospitals is not necessary.</td>
</tr>
<tr>
<td>2. Usefulness in improving patient outcomes</td>
<td></td>
</tr>
<tr>
<td>2A. Based on established clinical recommendations</td>
<td><strong>For process measures, there is good evidence that the process improves health outcomes.</strong> For outcome measures, there is good evidence that there are processes or actions that providers can take to improve the outcome.</td>
</tr>
<tr>
<td>2B. Potentially actionable by user</td>
<td><strong>The measure addresses an area of health care that potentially is under the control of the physician, health care organization, or health care system that it assesses.</strong></td>
</tr>
<tr>
<td>3. Measure design</td>
<td></td>
</tr>
<tr>
<td>3A. Well-defined specifications</td>
<td><strong>The following aspects of the measure should be well defined: numerator, denominator, sampling methodology, data sources, allowable values, methods of measurement, and method of reporting.</strong></td>
</tr>
</tbody>
</table>
| 3B. Documented reliability                                                | **The measure will produce the same results when repeated in the same population and setting (low random error)** Tests of reliability include:  
   a) Test-retest (reproducibility): test-retest reliability is evaluated by repeated administration of the measure in a short time frame and calculation of agreement among the repetitions  
   b) Interrater: agreement between raters is measured and reported using the kappa statistic  
   c) Data accuracy: data are audited for accuracy  
   d) Internal consistency for multi-item measures: analyses are performed to ensure that items are internally consistent.                                                                                                                                                                                                 |
### TABLE 11. Desirable Attributes of Measures (continued)

<table>
<thead>
<tr>
<th>Attribute</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>3C. Documented validity</td>
<td>The measure has face validity: it should appear to a knowledgeable observer to measure what is intended. The measure also should correlate well with other measures of the same aspects of care (construct validity) and capture meaningful aspects of this care (content validity).</td>
</tr>
<tr>
<td>3D. Allowance for risk</td>
<td>The degree to which data collected on the measure are risk-adjusted or risk-stratified depends on the purpose of the measure. If the purpose of the measure is for continuous QI and professional accountability, then requirements for risk adjustment or risk stratification are not stringent. If the purpose of the measure is comparison and accountability, then either the measure should not be appreciably affected by any variables that are beyond the user’s control (covariates) or, to the extent possible, any extraneous factors should be known and measurable. If case-mix and/or risk adjustment is required, there should be well-described methods for either controlling through risk stratification or for using validated models for calculating and adjusting results that correct for the effects of covariates.(^\text{a})</td>
</tr>
<tr>
<td>3E. Proven feasibility</td>
<td>The data required for the measure can be obtained by physicians, health care organizations, or health care systems with reasonable effort and within the period allowed for data collection. The cost of data collection and reporting is justified by the potential improvement in care and outcomes that result from the act of measurement. The measure should not be susceptible to cultural or other barriers that might make data collection infeasible.</td>
</tr>
<tr>
<td>3F. Confidentiality</td>
<td>The collection of data for the measures should not violate any accepted standards of confidentiality.</td>
</tr>
<tr>
<td>3G. Public availability</td>
<td>The measure specifications are publicly available.</td>
</tr>
</tbody>
</table>

\(^\text{a}\) In some cases, risk stratification may be preferable to risk adjustment because it will identify quality issues of importance to different subgroups.


**Types of measures** - Measures may be calculated in various ways. The most common approach is to state the measure as a proportion. The measure is expressed as the number of individuals (or events) in the category of interest divided by the total number of eligible individuals (or events) in the group.\(^\text{39}\) The numerator is therefore a subset of the denominator. This type of measure often is referred to as **rate-based**.

**Example:** The denominator is all patients older than age 50 with a fracture, and the numerator is those denominator patients who had BMD testing or who were placed on pharmacotherapy for osteoporosis within three months of the date of the fracture.

In a second type of measure, the numerator is not a subset of the denominator. When the sources of data are different for the numerator and the denominator, the relationship is more accurately referred to as a **ratio**.\(^\text{39}\)

**Example:** Falls resulting in fractures per 1000 patient visits.

A third type is the **continuous variable** indicator, in which the value of each measurement can fall anywhere along a continuous scale.
Example: Time from diagnosis of osteoporosis to initiation of pharmacotherapy. Measures are useful in evaluating performance longitudinally and can be used to capture various dimensions of performance such as timeliness or efficacy. They can be structured to capture desirable or undesirable aspects of performance. For example, a measure could be used to determine whether patients’ discharge instructions included a prescription for a BMD test (desirable) versus discharge instructions that did not include a prescription for a BMD test (undesirable). Process measures focus on specific patient care interventions performed by health care professionals and are distinct from outcome indicators that measure the results of the patient’s interaction with health care professionals. Each has advantages and disadvantages, as described in Table 12.94

Table 12. Comparing Process and Outcome Indicators

<table>
<thead>
<tr>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Process Indicators</strong></td>
<td></td>
</tr>
<tr>
<td>1. They can directly measure what was done for an individual or group (e.g., screening mammography for detection of breast cancer).</td>
<td>1. They may have little meaning for patients unless the link to outcomes can be explained.</td>
</tr>
<tr>
<td>2. They can assess care within a relatively short time window (e.g., weekly or monthly for run charts, annually for some preventive services, episodes for acute and chronic disease care).</td>
<td>2. If the process measure is a rate, the “right” rate may not be known (e.g., emergency department use rates, procedure rates).</td>
</tr>
<tr>
<td>3. They can use relatively small sample sizes for common processes.</td>
<td>3. They are often quite specific to a single disease or a single type of medical care, so that process measures across several clinical areas or aspects of service delivery may be required to represent quality for a particular group of patients.</td>
</tr>
<tr>
<td>4. They can frequently be assessed unobtrusively (e.g., from data stored in administrative or medical records).</td>
<td></td>
</tr>
<tr>
<td>5. They can be influenced by clinically appropriate actions taken by the health care organization or clinician.</td>
<td></td>
</tr>
<tr>
<td>6. They can be interpreted by clinicians who may need to modify their care delivery.</td>
<td></td>
</tr>
<tr>
<td><strong>Outcome Indicators</strong></td>
<td></td>
</tr>
<tr>
<td>1. They tend to be more meaningful to some of the potential users of performance measures (e.g., consumers, purchasers).</td>
<td>1. They tend to be influenced by many factors that are outside the control of the health care organization.</td>
</tr>
<tr>
<td>2. They more clearly represent the goals of the health care system.</td>
<td>2. They may be insensitive for making health care organization comparisons, particularly if poor outcomes are rare (e.g., mortality rates for children).</td>
</tr>
<tr>
<td>3. They can provide a summary measure of the effectiveness of medical care across a variety of conditions, types of care, or processes of care.</td>
<td>3. They may require large sample sizes to detect a statistically significant difference.</td>
</tr>
<tr>
<td></td>
<td>4. They may require obtaining data directly from patients.</td>
</tr>
<tr>
<td></td>
<td>5. They may take a long period of time to observe.</td>
</tr>
<tr>
<td></td>
<td>6. They may be difficult to interpret if the process that produced the outcome occurred far in the past and/or in another health care organization.</td>
</tr>
</tbody>
</table>
Applications
Collecting measure data is useful for the following activities:
- To observe patterns and trends in performance and stability of processes within an organization over time with objective data.
- To capture distinct dimensions of performance.
- To evaluate multiple aspects of performance that are related to the selected improvement, which helps to ensure that attention focused on one aspect of a process does not result in deterioration of other aspects.\textsuperscript{13}
- To measure factors in addition to the clinical dimension (e.g., financial aspects of care) or patient satisfaction. Measuring performance on multiple dimensions simultaneously sometimes is referred to as a “balanced dashboard.”\textsuperscript{95-97}

Measures can be derived from guidelines, standards, or consensus statements (if available) and thereby can support the assessment of performance against evidence-based practice recommendations.\textsuperscript{98, 99}

Resource considerations
If new data elements are required for the measure, these would need to be collected either through enhanced fields in automated programs or manual data collection. This method may require some automated data retrieval and analysis capabilities. The steps associated with aggregating data elements to calculate indicator rates may need to be programmed. However, measures can be calculated manually if the volume of data is not too great and the calculation algorithm is not too complex.

Utilize an Externally Developed Performance Measurement System

Definition/description of method
The Joint Commission defines a performance measurement system as an entity consisting of an automated database that facilitates PI in health care organizations through the collection and dissemination of process and/or outcome measures of performance. Measurement systems must be able to generate internal comparisons of organization performance over time and external comparisons of performance among participating organizations at comparable times. Visit the Joint Commission’s web site for a list of performance measurement systems (www.jointcommission.org).

Donabedian described a clinical performance system (also known as a measurement system) as a tool for rational management that supports assessment of performance with an epidemiologic perspective.\textsuperscript{100} Data are reported at regular intervals (e.g., daily, monthly, or quarterly) to a central database at the measurement system, most often in electronic formats. However, submission of hard copy data collection forms also is possible. The performance measurement system analyzes and reports the organization’s performance on the indicators, and provides comparative data aggregated from other participants using standard or customized reports. It should be noted that, although there are currently no commercial external systems collecting and comparing rates derived from standardized osteoporosis management indicators used among different organizations, this system capability may be developed in the future and is presented here for discussion and consideration.

There is, however, an initiative sponsored by the American Orthopaedic Association (AOA) called “Own the Bone.”\textsuperscript{101} It is a web-based improvement initiative targeted towards management of fragility fracture and provides prompts and materials to providers. Hospitals and providers are able to receive real-time internal and external benchmarking reports to assess and improve their performance. See the text box, following, for more information.
THE AMERICAN ORTHOPAEDIC ASSOCIATION’S “OWN THE BONE” PROGRAM: REDUCING SECONDARY FRAILITY FRACTURES

The American Orthopaedic Association (AOA) noted the alarming statistics regarding the inadequate management of patients with osteoporosis and fragility fractures and responded by developing a quality improvement initiative entitled Own The Bone.

Own The Bone is a web-based quality improvement initiative that is designed to make it easy for providers to apply current evidence-based knowledge about bone health and osteoporosis to the care of patients who have sustained a fragility fracture. The program provides prompts and materials to make it convenient for health care providers to deliver educational materials, preventive guidelines, diagnostic testing, and treatment recommendations to these patients. In addition, users are able to receive real-time internal and external benchmarking reports to assess and improve their performance as compared to recommended evidence-based benchmark tools and goals.

The Own The Bone program identifies a fragility fracture as a sentinel event, which provides the physician and the medical team with a “teachable moment.” This is a unique opportunity to engage the patient and his/her family in a discussion about bone health, osteoporosis, and the need to prevent future fragility fractures.

Own The Bone:

- Involved the participation of 14 medical institutions nationwide in a 10 month pilot study as an attempt to encourage orthopaedic surgeons to take the lead in affecting the bone health management of patients with fragility fractures
- Was designed to document the improvement of physician management of such patients in order to reduce the risk of secondary fractures and enhance the quality of patient care
- Was also designed as a tool to unite health care professionals across multiple specialties to improve patient care
- Centers on a team approach based on the premise that involving and empowering a variety of healthcare providers is the best strategy for success
- Includes nine evidence-based quality measures for the prevention, diagnosis, and treatment of osteoporosis in patients with fragility fractures

Goals of this program were twofold: 1. documentation of baseline behaviors and practice patterns in management of patients who have sustained a fragility fracture, and 2. documentation of the ability of the Own The Bone program to improve patient care by increasing compliance with evidence-based treatment strategies for fragility fracture care.

Results

The pilot program documented significant improvement compared to baseline in most areas (see chart). The most significant change was seen in efforts to coordinate and enhance care. Specifically, efforts to educate patients regarding prevention of fragility fractures and primary care physicians about the risks of osteoporosis and secondary fractures nearly quadrupled. Similarly, patient education regarding the intake of calcium and Vitamin D more than doubled during the program. Excellent results were also seen in the education of patients regarding the benefits of exercise and smoking cessation.

There were two measures for which little improvement was documented. Fewer than 20% of patients had a bone mineral density test ordered at the time of discharge. Similarly, osteoporosis pharmacotherapy was initiated in fewer than 30% of eligible patients. Because there are many possible explanations for both situations, these measures must be addressed in future refinements of this program.
Application

Performance measurement systems are useful for the following:

- Internal PI activities for which no established data collection processes exist. For example, a system that measures patient outcomes over time often will provide detailed data collection tools and training manuals.
- Provision of comparative outcome data (comparison with other organizations or against benchmarks). Some systems apply statistical risk-adjustment techniques to certain outcome data.
- Meeting external demands for data for accountability purposes, such as those incorporated in the CMS Voluntary Reporting Program and NCQA HEDIS measures.

PI-1: Pharmaceutical Intervention 1 - initiation of pharmacotherapy in a postmenopausal woman with a BMD T-score less than -2 or a fracture of the hip or vertebra

PI-2: Pharmaceutical Intervention 2 – initiation of pharmacotherapy for a postmenopausal Caucasian woman with a BMD T-score greater/equal to -2 and less than -1.5 if one or more risk factors for osteoporosis (such as a history of prior fragility fracture) is present.

Based on the pilot study, there are best practices and other recommendations that should be considered when implementing a program of this nature. The Own the Bone Study was developed by the American Orthopaedic Association in consultation with Outcome Sciences, Inc. dba Outcome. The web-based system is TotalQuality™, Outcome, Cambridge, MA. For more information on the AOA’s Own The Bone program visit www.aoassn.org.

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Resource considerations

Resource requirements are varied and may range from sophisticated information systems to manual data collection. The benefits and costs should be explored when considering use of a performance measurement system. Some possible benefits of using a performance measurement system include:

- **Data collection.** In some cases, the performance measurement system may function “invisibly” by abstracting data from existing repositories such as administrative/billing data. In other instances, the system may provide hard-copy forms or specific software for direct data entry, or it may allow for the electronic transfer of data from the organization’s own databases to a central system database.
- **Data analysis.** Some systems are capable of providing sophisticated data analysis techniques that the organization does not have in-house.
- **Data interpretation.** Some systems may provide access to professional staff who can assist in understanding and interpreting the data.
- **Report production.** In addition to standard reports, some systems offer custom, ad hoc reporting options.
- **External comparison.** Systems generally aggregate data from other system participants, providing an opportunity for external comparison.

Some other issues to consider regarding participation in a performance measurement system include:

- **Cost.** There are generally charges associated with participation, although some systems have no specific participation fees (e.g., MDS, OASIS), and there are even a few instances in which the system provides some reimbursement to participants.
- **Predetermined measures.** Participants are sometimes limited to the measures offered within the system.
- **Lack of customization.** To enable comparisons between participants, measures must be standardized and individual customization may be limited or unavailable.
- **“Black box” analysis methods.** Some systems may provide risk adjustment where applicable, but will not share specifics of the methodology used with participants for proprietary reasons.

Section VI: Assessing and Analyzing Your Processes and Results

This section describes the assessment phase in the cycle for improving performance. Assessment of data means translating data into information one can use to make judgments and draw conclusions about performance. The assessment phase allows one to compare performance, determine causes, and set priorities for actions/interventions (baseline data assessment), and to evaluate the effect of actions (results of improvement interventions).

Broadly defined, the assessment phase includes the following processes and activities:

- Analysis of the problem
- Analysis of data
- Interpretation of the results of data analysis
- Display of data and results
- Dissemination of information.

Assessment also requires that performance (baseline or follow-up) be compared with some reference point. Examples of reference points include:

- Historical patterns of performance within the organization.
- Internal policies and procedures.
- Desired performance goals, targets, or specifications.
The performance of other organizations provided in external reference databases. Established practice guidelines, standards, and consensus statements.

Assessment is not a one-time activity. It is usually done at several points in the process such as problem identification, baseline assessment, and reassessment after intervention. In fact, assessment often continues beyond the immediate QI project time frame at regular intervals (e.g., annually or every six months) to ensure that desired levels of performance are maintained.

A. Using Quality Improvement Tools

The assessment phase is greatly facilitated by the use of the relevant QI tools. The tools provide an essential common foundation/structure for the analyses of problems and results and are useful for ensuring that the improvement activity is planned and systematic, based on reliable data and accurate analysis, and carried out with effective teamwork and communication. It is important to understand the purpose and capability of each tool (see definitions in Table 13, below) so they are appropriately used. Although developed for distinct purposes, the tools may be used in several stages of a project, including planning, identification of the problem, analysis of baseline and follow-up data, planning solutions to the problem, and evaluation of the results. A grid to help organizations select tools appropriate to the phase of the project is provided in Figure 4, page 96. Because space constraints do not permit an adequate discussion of the use and value of these tools, readers desiring more information may find the following texts to be helpful: Managing Performance Measurement Data in Health Care, The Team Handbook, and Using Performance Improvement Tools in a Health Care Setting, Revised Edition.

<table>
<thead>
<tr>
<th>Tool Name</th>
<th>Definition</th>
<th>Phases of Quality Improvement Process</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brainstorming</td>
<td>A structured process for generating a list of ideas about an issue in a short amount of time</td>
<td>Problem identification, Data analysis, Solution planning, Result evaluation</td>
</tr>
<tr>
<td>Affinity diagram</td>
<td>A diagram designed to help teams organize large volumes of ideas or issues into major groups</td>
<td>Problem identification, Solution planning</td>
</tr>
<tr>
<td>Multivoting</td>
<td>A voting process that narrows a broad list of ideas to those that are most important</td>
<td>Problem identification, Data analysis, Solution planning, Result evaluation</td>
</tr>
<tr>
<td>Selection grid (prioritization matrices)</td>
<td>A grid designed to help teams select one option out of several possibilities</td>
<td>Problem identification, Solution planning</td>
</tr>
<tr>
<td>Cause-and-effect diagram</td>
<td>A diagram designed to help teams picture a large number of possible causes of a particular outcome</td>
<td>Problem identification, Data analysis</td>
</tr>
<tr>
<td>Control chart</td>
<td>A plotting of data on a graph indicating an upper and lower control limit on either side of the average</td>
<td>Problem identification, Data analysis, Solution planning</td>
</tr>
</tbody>
</table>

“Continual improvement is an unending journey.” — Lloyd Dobyns and Clare Crawford-Mason, Thinking About Quality
### TABLE 13. Quality Improvement Tools: Definition and Use (continued)

<table>
<thead>
<tr>
<th>Tool Name</th>
<th>Definition</th>
<th>Phases of Quality Improvement Process</th>
</tr>
</thead>
<tbody>
<tr>
<td>Run chart</td>
<td>A plotting of points on a graph to show levels of performance over time</td>
<td>Problem identification Data analysis Results evaluation</td>
</tr>
<tr>
<td>Check sheet</td>
<td>A form designed to record how many time a given event occurs</td>
<td>Data analysis</td>
</tr>
<tr>
<td>Flowchart</td>
<td>A diagram illustrating the path a process follows</td>
<td>Problem identification Data analysis Solution planning</td>
</tr>
<tr>
<td>Scatter diagram</td>
<td>A plotting of points on a graph to show the relationship between two variables</td>
<td>Data analysis Result evaluation</td>
</tr>
<tr>
<td>Pareto chart</td>
<td>A bar graph depicting in descending order (from left to right) the frequency of events being studied</td>
<td>Problem identification Data analysis Result evaluation</td>
</tr>
<tr>
<td>Histogram</td>
<td>A bar graph displaying variation in a set of data and distribution of that variation</td>
<td>Data analysis Result evaluation</td>
</tr>
</tbody>
</table>


### FIGURE 4. Selection Grid: Improvement Tools

<table>
<thead>
<tr>
<th>Tool Selection Grid</th>
<th>Tool</th>
<th>Phase of Problem-Solving Activity</th>
<th>Evaluating Indicators</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Problem Identification</td>
<td>Data Analysis</td>
</tr>
<tr>
<td>Brainstorming</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Cause and Effect</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>(Fishborn Diagram)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Check Sheet</td>
<td>X</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Control Chart</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Flowchart</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Affinity Diagram</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Histogram</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Multivoting</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Pareto</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Run Chart</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Scatter Diagram</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Selection Grid</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Prioritization Matrix</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Task List</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
</tbody>
</table>

Many of these tools were originally developed for use in industrial quality control. The application of industrial QI methodologies to health care was tested successfully by the National Demonstration Project on Quality Improvement in Health Care. This project paired industrial quality experts with teams from 21 health care organizations. The results are reported in *Curing Health Care: New Strategies for Quality Improvement* and summarized in the text box, below.

**TEN KEY LESSONS FROM THE NATIONAL DEMONSTRATION PROJECT ON QUALITY IMPROVEMENT**

1. QI tools can work in health care.
2. Cross-functional teams are valuable in improving health care processes.
3. Data useful for QI abound in health care.
4. QI methods are fun to use.
5. Costs of poor quality are high, and savings are within reach.
6. Involving doctors is difficult.
7. Training needs arise early.
8. Non-clinical processes draw early attention.
9. Health care organizations may need a broader definition of quality.
10. In health care, as in industry, the fate of QI is first of all in the hands of leaders.


**B. Analysis of Data**

Analysis involves sorting, organizing, and summarizing data into a form that enables people to interpret and make sense of the raw data. Understandably, raw data should not be used to draw conclusions about a process or outcome.

Typically, the data to be analyzed will have been entered (either directly from the data sources or secondarily from paper forms) into an automated database software program such as a spreadsheet (e.g., Lotus 123®, Microsoft Excel®, Microsoft Corporation, Redmond, WA) or a database management and analysis software package (e.g., SAS [SAS Institute Inc., Cary, NC] or others).

Data analyses can be done through the use of relatively simple descriptive statistics (e.g., medians, means and SDs, frequency distributions, proportions) or more complex, inferential techniques. Analyses can involve single variables, two variables (e.g., bivariate correlations), or multiple variables (e.g., multiple regression analyses).

Analysis of patient outcomes sometimes requires multivariate statistical techniques to risk-adjust for variables outside the health care organization’s control (i.e., intrinsic patient factors) that are related to the outcome of interest. For example, the outcome of decreased osteoporosis medication compliance may be influenced by patient beliefs and attitudes, which often are outside the control of the health care organization. More information on risk-adjustment approaches for performance measurement data can be found in *Risk Adjustment for Measuring Healthcare Outcomes*.

The sophistication of the analyses and ability to draw inferences from a sample by using statistical tests depend on many factors, including:

- The design of the study
- The quality of the data
- The sample size
- The level of data collected (e.g., patient, unit, organization)
- The underlying distributions of the variables (e.g., normal/Gaussian versus binomial)
- The type of data to be analyzed (nominal, ordinal, interval, ratio)

*A statistical analysis, properly conducted, is a delicate dissection of uncertainties, a surgery of suppositions.*

— M. J. MORONEY
The availability of statistical analysis programs
Familiarity of the analyst with statistics and data analysis techniques
It is recommended that individuals without a strong background in data analysis seek guidance from experts within the organization (e.g., a statistician, data analyst, or other QI professional) or consider use of an outside consultant. Keep in mind that complex analyses are not necessarily better for QI purposes. Often, simple descriptive statistics (means, SDs, and proportions) are more revealing and useful for improvement.

One well-known approach to data-driven evaluation of processes is the use of SPC. SPC is the application of statistical techniques such as control charts to the analysis of a process. It is used to determine whether the process is functioning within statistical norms (in control). It is particularly useful for distinguishing between random variation in a process (common cause variation) and changes due to specific occurrences (special cause variation). For more information on this topic, refer to the literature on statistical process control. A few references include Carey and Lloyd, Wheeler and Chambers, Grant and Leavenworth, and Sellick.

C. Interpretation of the Results of Data Analysis

This often-overlooked activity is an essential component of translating data into information. Defined simply, “data are numbers; information is what the numbers mean.”

O’Leary reports that data interpretation and dissemination are enhanced when the person(s) involved (i.e., the interpreter) demonstrates certain personal and professional attributes. These include:

- Problem-solving skills
- Thoroughness
- Open-mindedness
- Awareness of one’s own limitations
- A healthy degree of skepticism
- The ability to collaborate with other people
- Strong communication skills
- Numeracy (the ability to think and express themselves in quantitative terms)
- Computer literacy

One suggestion for enhancing interpretation involves narrowing the scope of interpretation to a workable amount of focused data (e.g., specific indicator rates or percentages) rather than all available data at once. Another important step in the interpretation process is evaluating the strength of data according to five aspects: 1) their clinical relevance to multiple stakeholders, 2) the range of health care processes and outcomes that they address, 3) the degree of reliability and validity of the methods and findings, 4) the degree of variation (fluctuation in processes and spread/dispersion around an average value), and 5) how much control providers have over the process or outcome measured by the data.

Interpreting the results of multivariate statistical analyses can be complicated; it often is helpful to seek advice from statisticians. For example, when determining the statistical significance of the results, the experts remind us that a P value of less than 0.05 is not a magical number; P values can be substantially affected by sample size and variance. In some cases, P values between 0.05 and 0.10 can signal important findings.

Another important issue is the difference between statistical significance and clinical importance. Clinicians need to judge whether or not the results are clinically significant—a decision that often is independent of the level of statistical significance. For example, comparing a mean 85% compliance with BMD testing for one large department receiving in-service education on osteoporosis management principles with a mean score of 14% in a similar control group may be statistically significant but clinically insignificant and unacceptable relative to the target level of performance.
D. Display of Data and Results

For interpretation and dissemination to be effective, it is essential to convey the findings and key messages as clearly and accurately as possible. Several considerations in selecting data displays include:

- Who is the audience?
- What is the most important message? (Do not drown the audience in data.)
- What do you need to present a complete and accurate representation of your findings? Be careful to avoid the pitfall of emphasizing only the positive.
- What graphical display capabilities do you have?

The most commonly used display tools are the pie chart, bar chart, and line graph.

Pie charts are most useful for displaying frequencies (or percentages) of single items that add up to the total number (or 100%). Bar charts are effective when displaying differences between groups (on the horizontal axis) in frequencies or percentages. Line graphs are particularly useful for spotting trends in a process.107

Akin to the concept of multivariate analyses, more advanced data display tools are useful for demonstrating multiple findings (e.g., rates, priorities, outcomes) on the same page. Examples of multiple measure display tools include the balanced scorecard, a dashboard display, a performance matrix, a radar chart, and a stratified multivariable display. Additional information on these data display tools can be found in Tools for Performance Measurement in Health Care: A Quick Reference Guide.107

Displays of data should be as clear and easy to read as possible. For example, use of the three-dimensional option when displaying the bars of a histogram can make it more difficult to determine the y-axis intersection. All legends and axes should be clearly labeled because the audience may not take the time to read accompanying text or they may not grasp the point(s) without subsequent reference to the material. The scale of the horizontal (x) and vertical (y) axes should be appropriate to the range of possible values. For example, depicting a change over time of 10% looks very different (and potentially misleading) on a vertical axis scale ranging from 50 to 70 than on a vertical axis scale ranging from 0 to 100 (Figure 5, below).

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**Figure 5. Using Appropriate Scales on Graphs**

This figure shows that using different vertical scales can affect the perception of the change in scores.

E. Dissemination of Information

Given that substantial time and resources have been invested to collect and interpret the data, it is important to share the findings as widely as is appropriate. Disseminating the results of the analysis process helps raise awareness in the organization of how it is performing with respect to osteoporosis management. Strategies or formats for dissemination include:

- Verbal representation (e.g., lecture, presentations at staff meetings, other gatherings).
- Written reports (e.g., published articles, newsletter).
- Visual displays (e.g., posters, story boards).
- Electronic dissemination (e.g., organization-wide Intranet, external Internet using an e-mail subscriber list).

It is important to know your organization and how information is best received. Think of creative ways to communicate your results. Make the learning experience interesting—even fun. When possible, use multiple methods such as a verbal representation and written report. Consider sharing your experiences (both successes and challenges) outside your organization by submitting an article to a journal.

Section VII: Improving Your Performance

This section reviews the steps related to designing and instituting actions or interventions (design/act) to achieve desired improvements. Interventions can vary widely from changing structural aspects that support osteoporosis management (e.g., office visit flow sheets, electronic reminders) to adding/enhancing care processes (e.g., assessing osteoporosis education).

A. Designing an Osteoporosis Improvement Intervention

After the team has completed analysis of data gathered to assess current practice, hypothesized root causes, and prioritized/selected opportunities for improvement, the team can begin to plan interventions. These interventions will comprise specific actions, such as implementing an educational program for patients and staff, and are to be based on the results of baseline measurements. Careful planning of the intervention will help ensure that it can be accurately evaluated for success. Aspects of implementation to consider include designing the intervention, conducting a pilot test before widespread application, and identifying an approach to measure the impact of the intervention(s) before integration into normal organizational processes.\(^\text{107}\)

Designing interventions will involve detailed planning of all aspects of the intervention such as developing or selecting written materials and defining changes to care processes. Other planning considerations include deciding who will be involved in testing, what information they will need, and how will it be communicated. Roles and responsibilities of project team members and other champions of the improvement intervention should be clearly defined. Details of operationalizing the intervention, projected timetables, and identification of measurable success factors also are important considerations. If target performance goals are established for the intervention, care should be taken that these do not represent levels below established standards of care, regulatory requirements, or other requirements when these are applicable. A target performance goal can serve as a reference point for measuring the success of the intervention.

Assessing the educational needs at your organization is an important part of the evaluation of current practice. Although education alone may not change care, improvements are unlikely to occur without it. When designing educational interventions consider the needs of:

- **Clinicians.** Provide a solid foundation for staff to practice good osteoporosis management and continually reinforce these practices through an initial program and regular updates. Tailor programs as necessary based on needs.
identified through assessments and support staff attendance by providing time. Changing clinician behavior also will require the influence of role models, the application of theory to actual clinical practice situations, and feedback on performance.

**Patients.** Tailor the extent of information based on needs (e.g., low bone mass patients need more comprehensive dietary information than patients without identified low bone mass). Use results of knowledge and attitude assessments to evaluate unique patient needs, including reading and language skills, education, and so on. Use a variety of approaches such as printed materials, video, in-house TV station, and one-on-one teaching.

For example, consider the steps involved in planning an educational program about osteoporosis management for staff. Specifics of the program content must be developed and a method of delivery determined (e.g., lecture, self-directed learning, teleconference). Staff must be identified for participation, the success factors determined (e.g., a minimum test score on a posttest), and a timetable established for staff attendance.

There are many types of interventions to be considered. The Cochrane Collaboration is an international not-for-profit organization that prepares, maintains, and promotes, among other topics, systematic reviews of the effects of health care interventions. The Cochrane Effective Practice and Organisation of Care (EPOC) Group is one of the review groups in the Cochrane Collaboration; EPOC conducts systematic reviews of interventions to improve professional practice and the delivery of effective health services. They have identified several specific types and sub-types of interventions, including:

- Continuing education and quality assurance
- Distribution of educational materials
- Educational meetings
- Educational outreach visits (use of trained persons to meet with providers in their practice)
- Patient mediated interventions (new information from patients collected and given to the provider for action)
- Audit and feedback
- Reminders (verbal, paper, or electronic prompts)
- Organizational interventions
  - Provider-oriented
    - Clinical multidisciplinary teams
    - Formal integration of services
    - Skill mix changes (e.g., ordering done by pharmacists rather than physicians, nurses performing dietary education)
    - Communication between distant health professionals (telephone or fax links)
  - Patient-oriented
  - Structural
    - Changes in care settings
    - Changes in medical records systems
    - Changes in staffing structures

Further information may be accessed at: www.mrw.interscience.wiley.com/cochrane/cochrane_clsysrev_subjects_fs.html.

**B. Testing and Implementing an Osteoporosis Improvement Intervention**

After designing all aspects of the intervention, it is helpful to conduct a pilot test before full implementation to identify problems that could affect the success of the intervention. Results of the pilot test may suggest the need to change aspects of the intervention’s design, implementation process, or evaluation approach. Address-
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... these issues early before proceeding with large-scale application of the intervention can prevent implementation failures, an unfortunate outcome that is costly in terms of both money and staff morale. It is worth noting again that improving performance is a repetitive process, and results may lead you to redesign the intervention and conduct further testing. Another benefit of the pilot test is that the results can serve to persuade skeptics and cement support from leadership to expand the improvement intervention.

As has been previously discussed, osteoporosis care can be the responsibility of multiple disciplines, departments, and clinicians as well as patients. Therefore, the success of interventions will be enhanced by securing commitment from key individuals who can serve as champions during implementation in day-to-day practice. This commitment is best secured by involving all stakeholders at the outset of the project.

C. Monitoring for Success

After implementing changes, close monitoring will be required initially to assess whether the intervention is meeting expectations and targeted improvement goals. Collection and analysis of measurement data will help in evaluating the appropriateness of the project goals. Data may suggest that the goals need to be adjusted. Monitoring also will help determine whether the intervention is being implemented consistently across the organization and will highlight areas needing additional support.

Influences external to the implementation process should be considered for possible impact. These include organizational factors such as mergers, ownership/personnel changes, or reorganization as well as other significant environmental changes (e.g., regulatory or reimbursement). Ongoing monitoring of PI literature and new osteoporosis findings and guidelines will alert the organization of the need to make adjustments as osteoporosis management and treatment options evolve.

After the success of the intervention has been established, the next priority is to ensure that the improvements are maintained. Again, measurement will be a critical factor in evaluating the intervention over time. Although it is necessary to determine that performance continues to meet desired goals, it may be possible to reduce the intensity (scope and frequency) of the measurement activity. Determining the level of monitoring necessary is part of ensuring sustained success.

D. Sustaining Change

A PI initiative is successful when the improvements become a permanent part of the organization’s routine. When an initiative succeeds, temporary changes in practice become operational processes (e.g., clinical pathways). Be aware, however, that change in practice behavior and improved outcomes can lag months to years behind improvement efforts.

It is important to set goals for ongoing improvement. For example, if initial implementation of the intervention was of a limited scope, it could expand to additional areas in the organization or across the entire organization. Measurement data might suggest other improvement opportunities that could be acted on. Performance goals might need to be raised. How does your organization’s performance compare with that described in external references, if available? This is the time to secure a commitment for those resources and approvals necessary to maintain progress.

As performance across health care organizations improves, the “bar is raised” and ongoing attention will help ensure that practices remain current. Also, new advances will lead to new opportunities.

Finally, success should be celebrated. Communicating improvements effectively, and in a timely and ongoing way, will help to reinforce the permanency of the change. Positive reinforcement is a strong motivator. Recognize participants and share accomplishments with others in your organization through formal (e.g., employee spotlight, staff recognition day, poster displays, newsletters, Intranet) and informal (personal visit by organizational leaders, special lunch or treats) means.
Section VIII: Understanding Factors That Affect Organizational Improvement

This section examines the potential of various factors to enable change (i.e., to facilitate improvement) or to be a barrier to change (i.e., to inhibit improvement). Also included is how the principles of total quality management can be applied to improving osteoporosis management performance.

A. Factors That Influence Change

Many factors influence an organization's ability to implement change and improve performance (see Figure 6, below). These factors can be grouped into the following four categories:
- Patient factors
- Clinician factors
- Organizational factors
- External/environmental factors

Many of these factors can be either barriers or enablers, or both barriers and enablers under some circumstances. A particular factor's degree of influence will likely vary according to the health care setting. For example, family factors that affect compliance with osteoporosis dietary recommendations are likely to have greater influence in the home health environment than in the long term care setting.

Key to an effective improvement initiative is maximizing the influence of enablers and minimizing the influence of barriers. Each organization may have unique challenges that will need to be addressed (such as restructuring or new computer systems). The following sections describe issues that have been identified in the literature.

Patient Factors

A patient's beliefs and perceptions about osteoporosis are likely to influence their behavior and compliance with recommended approaches. In a recent study...
for compliance with osteoporosis pharmacotherapy in 10,566 women by Bocuzzi and colleagues, persistence at 12 months was poor – 23% for alendronate, 19.4% for risedronate, and 16.2% for raloxifene.\textsuperscript{116} In addition to cost factors, it is thought that poor compliance is a result, in part, of a lack of perceived effect, since patients do not have symptoms and are unable to detect a direct medication effect.\textsuperscript{117}

Further, patients with osteoporosis who do not believe in their diagnosis are unlikely to be compliant with treatment.\textsuperscript{118} In the PHOTOS study, the group of women who perceived themselves as being ill from osteoporosis (many of whom had already sustained a fracture) were highly motivated compared with the group who considered themselves healthy and were not afraid to have a fracture.\textsuperscript{119}

Some evidence suggests that greater communication between patients and health care professionals may improve treatment adherence. On the other hand, patients and their families can be powerful allies and an effective force for change in promoting improvements. Due in part to the increased availability of information from sources such as the Internet, patients have become more equal partners in determining health care choices.\textsuperscript{91} Patients have increased knowledge and expectations specific to their treatment. The prominence of osteoporosis-related issues in the media has led to increased public awareness of the issues of osteoporosis management. Patient and family involvement in self-help organizations (e.g., the NOF, Foundation for Osteoporosis Research and Education [FORE]) also has increased the visibility of these issues.

**Clinician Factors**

Clinicians maintain a pivotal role in changing osteoporosis management practice. Clinicians can be defined broadly to include practitioners who are involved in clinical practice or clinical studies as well as clinical leaders in executive positions.

On the positive side, changing osteoporosis management care begins at the bedside. Therefore, clinicians are critical forces for improvement. Advances in osteoporosis specialty education and other educational options, such as seminars, have produced a cadre of clinicians with heightened awareness of, and expertise in, osteoporosis management.

Numerous professional organizations promote scientific approaches to practice, such as the NOF, International Osteoporosis Foundation (IOF), AACE, American College of Rheumatology (ACR), AOA, and ASBMR. Journals include articles on osteoporosis management, such as the *Journal of Bone and Mineral Research*, and others. There also is a proliferation of clinical texts, guidelines, position statements, and evidence-based practice recommendations.

**Organization Factors**

Organizations can impede improvement in osteoporosis care in ways that may not be obvious, yet are highly influential. Sometimes, well-intended policies and procedures can hinder the process. Documentation forms may not have a space for entry of osteoporosis-related findings. Standing orders may be outdated compared with current recommendations. Computer-generated discharge instructions may not include osteoporosis-related items.

Clearly, adequate resources are essential for a successful effort. These include, but are not limited to, the dedication of staff and equipment resources for the improvement initiative. The regular availability of appropriate medications, supplies, and equipment needed in daily patient care is important to organizational improvement. For example, insufficient numbers of home safety checklists could lead to delays in patient instruction for safety. Conversely, ready availability of some items can be counterproductive. For example, stocking of dietary instruction sheets that do not specifically address calcium and Vitamin D food sources can reinforce established patterns of inadequate calcium intake, when specialized instructional materials are needed that address these specific nutrients.

Of course, the most important resource issue is staffing effectiveness, which includes staffing levels, experience, and education of nurses and other direct and
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indirect care staff. When decreased numbers of professional staff (or increased numbers of non-clinicians) are caring for increased numbers of patients, it can be difficult to give osteoporosis-related education the attention it deserves. Similarly, staff turnover can have a negative effect on educational interventions and continuity of care, and organizational structure and culture also influence improvement activities.

There is a greater likelihood of success when leadership is interested and involved in the initiative. The literature shows that change is most effective when primary change agents (change champions) provide clinical leadership. Sound management practices play a role as well. For example, recent studies of long-term care organizations have found that certain characteristics of top management, such as job tenure, educational experience, and professional involvement, appear to affect the adoption of innovative practices. Computerization also can be an effective tool for change by supporting consistent documentation, on-line knowledge, analysis, and timely feedback.

Finally, some organizations have a structure and culture that embraces change. Organizational change has been studied extensively in the organizational management field, and various theories and strategies have been developed. For example, Zaltman and Duncan identified the following four strategies for implementing change in organizations:

1) reeducation, which is based on unbiased presentation of fact and assumes that rational people will adjust behavior accordingly
2) persuasion, which attempts to bring change through bias in structuring and presentation of information (i.e., selling an idea)
3) facilitation, which involves interventions designed to make change easier for individuals who already recognize the problem and agree on a remedy
4) power, which involves the use of sanctions or coercion to implement and maintain change

Beyer and Trice identified seven stages that organizations experience during a change process: 1) sensing of unsatisfied demands, 2) search for possible responses, 3) evaluation of alternatives, 4) decision to adopt a course of action, 5) initiation of action within the system, 6) implementation of change, and 7) institutionalization of the change.

For further reading/information on organizational change, the reader is directed to any of the above citations or to any of the abundant topical literature, including “TQM and Organizational Change and Development” in Total Quality Management in the Social Services; Theory and Practice.

External Factors

Patients, clinicians, and organizations are subject to influences exerted by the external environment. Compared with other countries, the U.S. has a pluralistic health care system. This system, which emphasizes freedom of choice, also unfortunately increases fragmentation of care, thus complicating the effort to provide individual patients with well-coordinated care across settings over time.

Payment mechanisms relating to medications and specialized osteoporosis diagnostic tests, treatments and services are not always designed to optimize osteoporosis management. For example, payment mechanisms for BMD testing do not encourage performance of the test while an acute inpatient; discharge orders for performance of a BMD test after fragility fracture is therefore encouraged, thus compounding the difficulty of assessing patient compliance with the order and accurately assessing prevalence of needed testing.

In part, through increased visibility in the media and advertising, public opinion and attitudes toward osteoporosis prevention, detection, and treatment may have begun to change. Similarly, the advances in scientific research, as well as the explosion of electronic and written health-related materials for both consumers and professionals, have greatly enhanced the knowledge base about the need for proper osteoporosis management.
B. Improving Osteoporosis Management through Total Quality Management Principles

Though this monograph has emphasized continuous QI using a structured process, it is worth noting that continuous QI is one element of the overall principle of total quality management. W. Edwards Deming, who is often considered “the father of modern QI,” iterated 14 points of quality management in his landmark book, Out of the Crisis. The effectiveness of organizational improvement initiatives will be enhanced by application of many of the points contained within these general principles.

THE 14 POINTS OF TOTAL QUALITY MANAGEMENT APPLIED TO IMPROVING OSTEOPOROSIS MANAGEMENT

1. Create constancy of purpose for improvement of product and service. Concentrate on a long-term plan based on a patient-focused mission (e.g., providing patients with follow-up osteoporosis care). Consistently model the vision of the organization (e.g., each person is a unique individual with certain rights). Enable staff to continuously improve costs, services, and patient satisfaction through well-designed osteoporosis management plans. Invest in a plan for continuing education and a system of rewards to encourage innovation in staff. Treat continuous improvement of osteoporosis management as an ongoing obligation to the patient.

2. Adopt the new philosophy. Quality osteoporosis management must become a driving passion of the organization or entity, so that suboptimal osteoporosis management in any care setting is immediately recognized as incompatible with the institution's mission and unacceptable to all of its staff and physicians.

3. Avoid dependence on inspection only to achieve quality. Traditionally, errors and problems are discovered after the fact through a process of quality assurance (inspection). This inspection process must be replaced with an improvement process that prevents errors and problems. Stop endless data collection on osteoporosis measures that are not fully met, and establish an osteoporosis care committee to analyze and synthesize the data you already have; develop plans to correct current osteoporosis problems and prevent the occurrence of new problems.

4. Avoid the practice of awarding business on price alone. Quality outcomes are possible only when quality materials, supplies, and processes are used. Consider long-term cost and appropriateness of products rather than just their purchase price. Cultivate long-term relationships with vendors, rather than simple short-term purchasing relationships. This requires that the supplier must consistently meet the needs of the organization and commit to continually improving its product (e.g., educational material suppliers become partners in providing comprehensive osteoporosis care by requesting input on how their product can be improved to help clinicians provide better osteoporosis care). Many suppliers offer a variety of free consultative services and sponsor educational programs for institutions that are interested in improving osteoporosis management. Further, use of one supplier for educational materials will help reduce variability in educational content provided to patients.

5. Constantly improve every process for planning, implementation, and service. Improving osteoporosis management is not a one-time effort. Teamwork is essential. Approve the establishment of an interdisciplinary osteoporosis care committee. Empower front-line staff to contribute to the improvement process (e.g., encourage them to serve as members of the osteoporosis care committee), to constantly look for ways to reduce waste and improve quality, and to become accountable for osteoporosis management (e.g., become an osteoporosis resource nurse).

6. Institute teaching in the workplace. On-the-job training alone encourages worker-to-worker propagation of practice. Many practices are faulty and outdated (e.g., promoting the idea that a fragility fracture is a “benign” event). Teach and re-teach (continuing education) front-line staff members the important aspects of osteoporosis management, give adequate support for providing effective osteoporosis education, and measure the effectiveness of the training. Assign new staff members to trained preceptors who will perpetuate quality performance. Remember to encourage, not drive, staff. Adjust the preceptor’s workload so that quality training is possible.
7. Ensure qualified leadership.
The job of management is to lead. Leading is moving staff toward a vision, managing is helping them do a better job (e.g., ensure that osteoporosis care committee members attend meetings).

8. Drive out fear.
When staff fear failure, embarrassment, or retaliation, they are unwilling to make suggestions and recommendations for change. This results in a lower level of quality. Consider and value all staff suggestions. Encourage contribution. Appreciate that front-line staff members are “in the trenches” and have invaluable knowledge of how to improve osteoporosis management.

The goals of the various departments must complement one another, or quality is jeopardized. Foster teamwork by dismantling systems that stop staff from working together to accomplish a project. Help staff understand the needs of other departments and work together toward the organization’s vision. Promote processes that support the vision (e.g., order BMD testing for fracture patients when they are discharged to home from the Emergency department. This helps to avoid the patient or the primary care physician not addressing detection of underlying osteoporosis in the post-discharge period and helps to avoid one source of gaps in care and treatment).

10. Avoid slogans, exhortations, and targets.
Avoid using derogatory or ambiguous slogans such as “Get It Done!” These types of slogans provide no direction and may offend and repel some staff and physicians. Further, some problems are system-based and not in the immediate control of the worker. If slogans and motivational phrases are used, explain them (e.g., “Our slogan is ‘Preventing Frailty Fractures Is Easier than Treating Them.’” This means that we educate patients with low bone mass for home safety and dietary needs before they fall and sustain a fracture.). Let staff and physicians know exactly what is being done to make it easier for them to provide better osteoporosis management (e.g., post in all clinical areas a list of the names and numbers of educators, dietary counselors, and nurses available to help with osteoporosis education issues).

11. Eliminate numeric quotas.
Quotas place a cap on productivity and conflict with the continuous nature of QI. Osteoporosis issues and problems are ongoing and unending. Encourage staff to look for more than one problem to solve and more than one way to improve osteoporosis management. Eliminate numeric “targets” and instead exhibit leadership in achieving the objective.

12. Remove barriers to pride of workmanship.
delegate authority and responsibility to staff members to foster autonomy while promoting the philosophy of an interdisciplinary, interdepartmental approach to osteoporosis management. Avoid focusing on individual or department performance (e.g., osteoporosis management is everyone’s responsibility); support teaching nurses to manage side effects of osteoporosis medications.

13. Institute a vigorous program of staff education, continuing education and self-improvement.
Encourage staff members’ ongoing personal development even in areas not related to their jobs. Continually provide updated osteoporosis management information to staff and consider the need for updated osteoporosis management technology to improve performance (e.g., evaluate and reevaluate the way osteoporosis is being assessed and managed and update approaches on the basis of advances in osteoporosis knowledge and technology).

14. Take action to accomplish the transformation.
Put everyone, including top management, to work on sustaining the organization's new mindset (e.g., discuss the institution's philosophy of providing preventive and/or follow-up osteoporosis care with all new employees during their orientation and update long-term employees during their annual cardiopulmonary resuscitation and fire prevention recertification classes).

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